The cost-effectiveness of Intermittent Preventive Treatment for malaria in Gambian multigravidae, including examination of indirect costs

By
Pa Lamin Beyai

Supervisors:
Professor Anne Mills
Dr. Virginia Wiseman

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London School of Hygiene and Tropical Medicine
Health Policy Unit
Department of Public Health and Policy

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ABSTRACT

The aim of this thesis is to estimate the cost-effectiveness of intermittent preventive treatment of pregnant women (IPTp) with sulphadoxine-pyrimethamine (SP) to prevent Low Birth Weight (LBW) and anaemia due to malaria in pregnancy in Gambian multigravidae, including an examination of indirect costs. The study was piggy-backed on a Randomised Controlled Trial (RCT) of the effectiveness of IPTp conducted in the rural area of the country from July 2002 to February 2004.

The specific objectives are to:

i. Examine the cost-effectiveness of introducing SP as IPTp for malaria into normal antenatal care for multigravidae women in rural Gambia;
ii. Explore various methods of valuing indirect costs and assess the extent to which they affect the cost-effectiveness ratio; and
iii. Make policy recommendations as to whether to introduce SP as IPTp on cost-effectiveness grounds.

The rationale for the study is that both national and international policy makers need precise information to determine which intervention strategies are best for prevention and control of malaria in pregnancy, and which strategies represent good investment. They also need to know how the cost-effectiveness of such interventions compared to other public health interventions. Cost-effectiveness analysis (CEA) is a recognised tool for advising policy makers on the value of an intervention. However, in practice, there are few CEA studies of malaria in general and malaria in pregnancy in particular in developing countries. Previous CEA studies of IPTp in developing countries have been limited to primigravidae and secundagravidae. Moreover, most of them were conducted from the perspective of the provider without incorporating indirect or productivity costs. This could partly be due to lack of consensus on the issue of whether or not to include indirect costs.

The data required for the study was collected through several methods. For IPTp intervention costs to the health-care provider, antenatal clinic users and their families, a sample of 884 multigraviade were randomly selected from the main IPTp effectiveness trial sample of 2,688 recruited multigravidae. In addition, several sub-studies such as health facility studies for the IPTp intervention, a hospital study for treatment of LBW and anaemia, a time-use study and collection of secondary data were used to estimate costs. Time-use and employment surveys were used to measure the time and alternative values for unpaid work.

The costs data were combined with the effectiveness data from the trial to estimate incremental costs and consequences for Base case I (trial sample) and Base case II (non-users of bednets in trial sample).

The study results showed that the net costs of IPTp with SP for multigravidae with and without indirect costs were D1,221,771 and D1,887,607 respectively for Base case I. The inclusion of indirect costs led to a 68% increase in net costs in Base case I. The corresponding figures for Base case II were D315,933 and D453,620. The indirect costs in Base case II constituted a 44% increase in net costs. In terms of effectiveness, the DALYs averted in Base cases I and II were -125.8 and -0.13 respectively. So the intervention created resource losses. Sensitivity analysis conducted by varying key costs and effectiveness parameters showed the introduction of a haemoglobin test led to over 400% increase in net costs for both base cases; and reduction in number of doses led to around a 40% reduction in net costs. Except for the use of the opportunity cost method of valuing indirect costs in Base case I that led to a 12% decrease in net costs, the use of all other human capital wage rates led to a less than 10% change in net costs for both base cases.

Sensitivity analysis of giving IPTp to all pregnant women (primigravidae, secundigravidae and multigravidae) found that IPTp dominated the control for the two base cases. The domination remained regardless of whether indirect costs were included or not. However, the magnitude depended on the wage rate used in estimating indirect costs. The inclusion of indirect costs led to resource savings in the range of 9%-20% for Base case I and 10%-23% for Base case II. The general conclusion is that giving IPTp with SP to multigravidae alone is not cost-effective. However, some improvements in health outcomes were observed for those women who do not sleep under bednets. If IPTp were to be given to all pregnant women without regard to gravidae, IPTp was dominant with and without indirect costs. The resource savings varied according to the wage rate used. However, there may be a policy dilemma associated with giving IPTp to all women knowing that the trial showed it conferred no benefits, and even might carry some risks.

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DEDICATION

This thesis is dedicated to the memory of the following.

Father:	Foday Beyai
Mother:	Haja Fatoumata Gassama

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LIST OF ACRONYMS

AFPRCH	Armed Forces Provisional Ruling Council Hospital
ANC	Antenatal Care
CRD	Central River Division
CSO	Central Statistics Office
CSD	Central Statistics Department
CCS	Country Cooperation Strategy
CHN	Community Health Nurse
DHT	Divisional Health Team
DOSH	Department of State for Health
DOSFEA	Department of State for Finance & Economic Affairs
DOSWI	Department of State for Works & Infrastructural Development
ELBW	Extremely Low Birth Weight
VLBW	Very Low Birth Weight
GDP	Gross Domestic Product
HEED	Health Economic Evaluations Database
IEC	Information Education and Communication
IPD	Inpatient Department
IPTp	Intermittent Preventive Treatment for pregnancy
IMR	Infant Mortality Rate
KMC	Kanifing Municipal Council
LBW	Low Birth Weight
LRD	Lower River Division
MCH	Maternal and Child Health
MMR	Maternal Mortality Rate
MRC	Medical Research Council
MIP	Malaria in Pregnancy
MOH	Ministry of Health
MRC	Medical Research Council
NBD	North Bank Division
NBE	North Bank East
NBW	North Bank West
NBW	Normal Birth Weight
NGO	Non Government Organisation
NHA	National Health Accounts
NICE	National Institute for Health and Clinical Excellence

PER	Public Expenditure Review
OPD	Outpatient Department
PHPNP	Participatory Health Population and Nutrition Programme
RVTH	Royal Victoria Teaching Hospital
SRNM	State Registered Nurse Midwife
SP	Sulphadoxine-Pyrimethamine
TBA	Traditional Birth Attendant
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UN	United Nations
URD	Upper River Division
VHS	Village Health Services
VHW	Village Health Worker
WD	Western Division
WHO	World Health Organisation

CHAPTER 1: BACKGROUND OF THE RESEARCH

1.1 STATEMENT OF THE PROBLEM AND RATIONALE FOR THE STUDY

Rationale for Intermittent Preventive Treatment for Pregnancy (IPTp)

Malaria is a parasitic disease spread by mosquitoes and is endemic in parts of Africa, Asia and South America (RBM, 2002; 2003; Orton and Garner, 2005; Desai et al 2007). The prevalence of symptomatic malaria is higher amongst pregnant women when compared to non-pregnant women regardless of the setting, and it poses a severe threat to the pregnancy of any woman (Nosten et al, 2004; Brabin et al, 1988; Brabin et al, 1990; Meek et al, 2001, Crawley et al 2007). Out of approximately 50 million pregnant women worldwide who are exposed to malaria annually, over 30 million of them come from the African region (Crawley et al, 2007). Most non-pregnant women are semi-immune to *Plasmodium falciparum* malaria due to previously repeated infection, causing them to be asymptomatic even if they have parasites in their blood. Cases of clinical disease in non-pregnant women are often not severe (Whitty et al, 2005). However, immunity to malaria that is acquired before pregnancy is usually reduced in practice during pregnancy, particularly the first pregnancy, leading to greater risk of mortality (Anya, 2004). Those who do not have prior immunity to malaria infection are at even higher risk during pregnancy of complicated malaria and foetal loss (Shulman and Dorman, 2003; Luxemburger et al, 2001).

Susceptibility to malaria infection and the severity of clinical manifestations are therefore determined by the level of immunity before pregnancy; that in turn is affected by the intensity and stability of malaria transmission (Mutabingwa, 1994). Intensity of malaria transmission in Sub-Saharan Africa (SSA) ranges from holo-endemic to virtually zero. Those in highland areas, urban settings and much of South Africa may have little or no exposure to malaria before pregnancy and are therefore non-immune. In particular, malaria can cause maternal anaemia even in the absence of peripheral parasites. The level of acquired immunity also depends on the parity of the woman and HIV infection, which may further impair the efficacy of the immune response during pregnancy (Steketee et al, 1996b; van Eijk et al, 2002; van Eijk et al, 2003; Verhoeff et al, 1999).

The consequences of malaria in pregnancy for both the mother and her unborn child can be very serious (Steketee et al, 2001). According to Bellamy (2004), malaria in pregnancy is one of several causes of maternal, foetal and neonatal mortality worldwide. Malaria is directly or indirectly one of the leading causes of maternal and perinatal morbidity and mortality in SSA (Whitty et al, 2005; Menendez et al, 2000; Rogerson et al, 2000; Marchant et al, 2004).

It causes maternal anaemia to mothers and low birth weight (LBW) of infants born to mothers (Shulman et al, 2001a; 2001b) accounting for at least 5% of perinatal deaths in developing countries (Guyatt and Snow, 2004). Each year, there are at least 25 million pregnancies in malaria-endemic areas in SSA at risk of *Plasmodium falciparum* malaria infection during pregnancy (WHO, 2004).

A LBW newborn is defined as one that is born weighing 2500 grammes or less. In areas of stable transmission, malaria in pregnancy contributes to approximately 8% to 14% of LBW (Steketee et al, 2001; Steketee et al, 1996a; RBM, 2002; 2003), 8% to 36% of prematurity and an additional 13% to 70% of Intrauterine Growth Retardation (IUGR), depending on the level of risk (Steketee et al, 2001, RBM, 2002). Maternal malaria accounts for 30% of all preventable LBW during pregnancy and approximately 3% to 8% of all infant mortality (Steketee et al, 2001; Steketee et al, 1996a). Another pathway to LBW is severe maternal anaemia, which is also caused by malaria infection.

Anaemia in pregnancy is generally defined as haemoglobin level less than 11g/dl and severe anaemia is haemoglobin level less than 7g/dl (ORC Macro, 2005; http://encyclopedia.thefreedictionary.com). Malaria is a major cause of anaemia particularly in primigravidae, but other causes may also play a significant role particularly in secundigravidae. Primigravidae or gravidae one refers to a woman who is pregnant for the first time and a woman who has been pregnant more than once is referred to generally as multigravidae or more specifically as gravidae two (also secundigravida), gravida three, and so on (http://en.wikipedia.org/wiki). In areas of stable transmission, malaria in pregnancy contributes to approximately 2% to 15% of maternal anaemia (Steketee et al, 2001; Steketee et al, 1996c; SARA/USAID, 2001).

According to Guyatt and Snow (2001a), as many as 400 000 pregnant women may have severe anaemia because of malaria-infection in SSA. In holo-endemic areas — with a 5% severe anaemia prevalence — malaria accounts for approximately 18% of severe anaemia related deaths in primigravidae (Brabin et al, 2001) with the rest due to nutritional deficiencies, mainly iron, folate vitamin A and vitamin B12 deficiencies or HIV infection (Meek et al, 2001).

In their pursuit to control malaria, African leaders at an Organisation of African Unity (OAU) meeting in Abuja in April 2000 committed themselves to halving malaria mortality in Africa by 2010 and to also ensuring 60% coverage of pregnant women at risk of malaria by the year 2005 (WHO 2003a).

The first step to achieving this was the development of a strategic framework for controlling malaria by the WHO Regional Office for Africa (WHO/AFRO) which recommended a three-pronged approach of IPTp with appropriate drugs delivered at the antenatal clinic, use of ITNs and proper case management (WHO, 2003b, WHO, 2004a).

Earlier attempts to prevent malaria in pregnancy were through chemoprophylaxis using chloroquine. However, maintaining a high level of compliance and widespread chloroquine resistance made malaria-prevention difficult (Whitty et al, 2005). An attempt to overcome these problems brought about the concept of IPTp with Sulphadoxine-Pyrimethamine (SP). IPTp is based on the assumption that every pregnant woman living in an area of stable or unstable malaria transmission has malaria parasites in the blood or in the placenta and should therefore be treated to minimise the parasites' effect on the mother and her foetus (WHO, 2004). IPTp refers to the periodic administration of anti-malarials during pregnancy irrespective of the presence of parasites and/or clinical illness (Meek et al, 2001). The aim of IPTp is to clear the placenta of parasites and peripheral parasitaemia during the period of maximum foetal growth (24-36 weeks). Whether this is truly a matter of intermittent presumptive treatment as originally supposed, or of chemoprophylaxis with a long-acting drug (SP) or a mixture of the two, remains a matter for debate. SP, which is the drug of choice in many countries for IPTp, is a combination of two drugs with each tablet containing 500mg of sulfadoxine and 25mg of pyrimethamine (WHO, 2004). A single dose of SP consists of three tablets taken at once, preferably under direct observation by the health care provider. Fansidar is the most common brand of SP, but other brands such as Falcidin, Laridox and Maladox do exist. IPTp with SP is currently the most effective approach in the use of anti-malarial drugs during pregnancy and is particularly attractive for use in areas with a high level of chloroquine (CQ) resistance (WHO, 2004).

According to Whitty et al (2005), prescribing anti-malarial drugs, like many other drugs, is a balancing act. Malaria in pregnancy, which has adverse effects for both the mother and the foetus, should be treated with efficacious drugs, but also safe ones, so that they can clear the parasites without negatively affecting the health of the mother. SP as IPTp was found to be safe in the prevention of placental and peripheral malaria in primigravidae and secundigravidae in SSA. Although there have been worries about the safety of drugs in relation to the foetus, no compelling evidence exists to support the claim that any of the drugs currently being used as anti-malarial drugs have tetratogenic effects in humans, but in large part, this may be because there is no evidence either way (Whitty et al, 2005). SP has been used extensively in pregnancy, including as IPTp, but formal safety studies in pregnancy were limited (Ward et al, 2007).

Evidence showed that in over 2000 pregnant women treated with SP in the second and third trimester, the drug did not increase the risk of malformation or other adverse events in the foetus (Nosten et al, 2006).

There has been limited evidence that sulpha drugs may be linked to kernicterus when given to premature neonates (Silverman et al, 1956) but this has not been observed in studies where SP as IPTp was administered to mothers (Parise et al, 1998; Verhoeff et al, 1998; Shulman et al, 1999). Studies found no increased risk in spontaneous abortions or congenital defects because of *in utero* exposure to SP (Parise et al, 1998; Verhoeff et al, 1999). SP as weekly prophylaxis has been associated with rare and severe reactions (Miller et al, 1986), but there is no evidence that this risk is any greater in pregnancy (Newman et al, 2003). No adverse pregnancy consequences were found in instances where only Pyrimethamine was given alone (Morley et al, 1964).

In summary, SP based on present evidence is considered safe in the second and third trimesters of pregnancy (Newman et al, 2003; Nosten et al, 2006). Safety of multiple doses of SP in HIV infected pregnant women requires further evaluation as does SP when used in combination with antiretroviral drugs (Okereke, 1999). The safety of other anti-malarials for pregnant women such as tetracycline, doxycycyline, primaquine and halofantrine is not yet definitive and so their use has not been recommended (WHO, 2004). It has been noted that the lack of such evidence on the safety of other drugs does not mean that they have a complete clean bill of health for pregnant women (Whitty et al, 2005). The common trend is that, the newer the drug, the more likely it is to be efficacious. This is so because of lack of sufficient time for resistance to develop. However, the short time makes it impossible to provide sufficient data to guarantee their safety (Whitty et al, 2005).

An early study from Malawi (Schultz et al, 1994) showed that two doses of SP given during pregnancy substantially reduced the prevalence of placental malaria. Subsequent studies from Malawi reveal that IPTp with SP provided through routine antenatal services reduces LBW in primigravidae but not in multigravidae (Verhoeff et al, 1997; Rogerson et al, 2000). In Kenya, a controlled trial showed that IPTp with SP given two or three times during pregnancy reduced the prevalence of severe anaemia in primigravidae (Shulman et al, 1999). Other studies conducted in Kenya showed that IPTp has beneficial effects on LBW, although this is muted in HIV positive women (Parise et al, 1998). It has also been reported that the efficacy of two doses of SP is impaired in HIV infected pregnant women with three (Verhoeff et al, 1998) or more (Parise et al, 1998) doses needed to achieve sufficient levels of effectiveness.

It is on the basis of these empirical findings that WHO recommends IPTp with SP for all pregnant women resident in areas of medium or high malaria endemicity (WHO, 2002). Evidence of SP's efficacy as IPTp, demonstrated in Kenya and Malawi (Steketee, 2001; Shulman et al, 1999; Schultz et al, 1994; Parise et al, 1998) led to its adoption as policy in these countries. IPTp with two doses of SP (in the second and third trimester) has been shown to be effective in reducing placental parasitaemia, thereby improving birth weight (Gulmezoglu and Garner, 1999) and preventing severe maternal anaemia (Shulman et al, 1999) in primigravidae. Although one visit may not be sufficient for IPTp to be fully efficacious, the fact that 35%-95% of pregnant women in Africa attend antenatal clinics at least once during pregnancy presents a good opportunity for IPTp to reach as many pregnant women as possible (WHO, 2004).

However, most of the studies mentioned above were with respect to primigravidae and secundigravidae. Other studies considered all pregnant women without conducting separate efficacy analyses by gravidae. Thus, although IPTp with SP is recommended for women of all gravidae, there has been little evidence to support its use in multigravidae. Until very recently, there has been no trial that has specifically addressed the effectiveness of SP as IPTp for this group of women. This gap in the evidence base led to a randomised controlled trial in The Gambia to test the efficacy of IPTp using SP in multigravidae in rural areas. There are good theoretical reasons to think that IPTp may become less effective as the number of pregnancies increases. The impact of malaria causing anaemia in pregnancy decreases with each pregnancy. Therefore, whilst the risk of giving potentially teratogenic drugs in pregnancy stays steady in each pregnancy, the potential benefit may decrease. In some settings, the majority of pregnancies are in women who have had more than two children to term. The potential risk-benefit and cost-effectiveness of IPTp in multigravidae women is therefore a significant public health concern.

Malaria in The Gambia

Malaria in The Gambia remains a major public health problem, with associated social and economic implications (DoSH, 2003). The health burden is greater among pregnant women and children under five years, particularly in the rural areas where large numbers of breeding grounds favour a high vector population (Koram, 1993). Malaria is one of the leading causes of mortality and morbidity in the Gambia especially for children under five years (Greenwood et al, 1987). Although accurate figures are hard to come by, it is estimated that 2% of antenatal consultations and 40% of under-five visits to maternal and child health (MCH) services are due to malaria (DoSH, 2003). More than 20% of outpatient treatment has also been attributed to malaria (DoSH, 2001).

Furthermore, malaria is believed to be one of the main causes of severe anaemia in pregnancy with LBW deliveries of primigravidae in rural facilities estimated to vary between 18-30% of all births (DoSH, 2001).

The recently finalised Malaria Control Policy and Strategic Plan of The Gambia (DoSH, 2003a; DoSH, 2003b) aim to reduce the burden of malaria through well-targeted interventions with full community participation. The guiding principle is to ensure that the most vulnerable groups, pregnant women and children under five years, benefit the most. The policy specifically targets six programme areas, namely; case management, malaria in pregnancy, vector control, management and partnership, information education and communication (IEC) and advocacy, and surveillance and research (DoSH, 2003a). The officially recommended first line drug for treatment of uncomplicated malaria is chloroquine (CQ), and the second line drug is SP. Quinine is reserved for treatment of severe and complicated malaria. This is however likely to change because the government is considering a policy change on first-line malaria treatment from CQ to Artemisinin-Combination Therapy (ACT) with Coartem. The policy for Malaria in Pregnancy is to improve the outcome of pregnancy for mothers, the foetus and the newborn by following the WHO's approach of use of IPTp, ITNs and case management of malaria illness (DoSH, 2003). This should be done through provision and promotion of the cost-effective use of IPTp by all pregnant women, increased access to and promotion of the use of ITNs for all pregnant women, promotion of early antenatal clinic attendance, and prompt diagnosis and treatment of cases of malaria in pregnancy. Despite the high burden of malaria in pregnancy in The Gambia, there is no countrywide use of chemoprophylaxis as a preventive measure in general, or more specifically the use of SP as IPTp for pregnant women.

Rationale for measuring the cost-effectiveness of IPTp

Both national and international policy makers need precise information to determine which intervention strategies are best for prevention and control of malaria in pregnancy and which strategies represent good investment. They also need to know how their cost-effectiveness compares to other public health interventions. Economic evaluation methods, especially cost-effectiveness analysis (CEA), can provide vital clues to identify the interventions that represent the best value for money (Goodman et al, 1999a). However, in practice, there are few studies of CEA of malaria and only three for chemoprophylaxis or IPTp in pregnant women (Mills, 2005). Comparison of these studies demonstrates significant variations in cost-effectiveness depending on epidemiology, relative cost, existing infrastructure, scale of activity, compliance and coverage, managerial capacity, etc. (Goodman et al, 2001).

Limitations of the studies include their concentration on primigravidae and secundagravidae at the expense of multigravidae and their narrow perspective whereby only costs affecting health care providers were considered. Each of these issues limits the generalisability of results from one setting to another. There is need for an economic evaluation that builds upon the earlier work in a number of important ways. Firstly, in terms of the methodology, a broader definition of both costs and effects needs to be taken. Typically, costs have been narrowly defined as drug costs (provider perspective), rather than a societal perspective, i.e. wider costs borne by the health service provider, transport costs and time off work for patients and families of patients (i.e. time off work to accompany patients to health care facilities). Secondly, a societal perspective also implies that the consequences of IPTp — in terms of mortality and morbidity — need to be measured as well as the process of seeking care, such as satisfaction or otherwise of waiting times. Thirdly, most existing studies have examined the sensitivity of cost-effectiveness ratios to the level of compliance but studies need to go further to investigate other variables likely to influence cost-effectiveness such as indirect costs, efficacy rates and so on.

In an attempt to fill these gaps, an economic evaluation was piggy-backed onto the randomised controlled trial conducted in The Gambia to test the efficacy of IPTp using SP in multigravidae in rural areas. As outlined above, the potential effectiveness in multigravidae women may well be lower than in primigravidae and secundigravidae. This is important not only for the clinical risk-benefit analysis, but also for cost-effectiveness. If the effectiveness of the intervention is reduced and the same costs maintained, the cost-effectiveness is inevitably affected. The aim of the economic evaluation was to compare the costs and effects of adding SP as IPTp to normal antenatal care for multigravidae in The Gambia. There has not been a previous economic evaluation of this nature in developing countries. Cost-effectiveness analysis is a recognised tool for advising policy makers of the value of an intervention. However, there is no agreement on certain aspects of the methodology of CEA, especially the issue of whether or not to include indirect costs.

Rationale for investigating indirect costs

Indirect costs or productivity losses are defined as the costs of those resources for which no payment is made, but for which there is an alternative use that is of value to someone (Jacobs and Fassbender, 1998). In order to avoid confusion caused by the use of the term indirect costs by accountants to describe overhead costs, Drummond et al (2005) in their new framework replaced the term indirect costs with the term productivity losses.

However, the latter are still incorporated within the CEA framework (M. Drummond, personal communication, email 2006). The role of indirect costs or productivity losses in economic evaluation, and their estimation, have been contentious and debated widely (Drummond et al, 2005). The inclusion of indirect costs in CEA requires expanding the perspective of the intervention from patients or health services to societal. A societal perspective takes into account all the costs and consequences that occur because of an intervention and requires resources to be valued within the context of their societal opportunity costs.

There is disagreement amongst scholars with regard to the treatment of indirect costs in economic evaluation. The first school of thought comprises those who consider indirect costs important to be included in economic evaluation. However, different authors give different reasons and emphasis for doing so with potential implications on the transferability of findings from one setting to another. Jamison (1993) argued that the perspective of service users must be taken on board; Pritchard and Sculpher (2000) saw both paid and unpaid time as scarce resources that should be equally valued for all patients for ethical reasons; Posnett and Jan (1996) considered the value of unpaid time as an important element in the indirect cost of health care production especially given the shifting focus of health services from centralised to community care through early discharge; and Koopmanschap and Rutten (1996) argued that productivity effects are relevant as long as the estimates reflect the real economic impact of diseases and ignoring them denies the reality that production losses influence scarcity of resources. Other authors such as Phelps and Mushin, 1991; Creese and Parker, 1994; Haddix et al, 1996; base their arguments on maximising the efficiency of health care spending for the entire population and ensuring consistency between costs and consequences. From the reasons given above, only those who put forward arguments based on the importance of unpaid work may be relevant to developing country settings where such type of work is the norm.

The second school of thought argues that indirect costs should not be incorporated as part of economic evaluation and give contradictory reasons for excluding them. Gerard and Mooney (1993) argue that expressing health effects in health-related quality of life measures, such as the Quality Adjusted Life Years (QALY), removes the logic of including non-health care costs in the analysis because non-health care resources such as leisure and working time have a range of alternative uses other than health-producing activity and therefore cannot be adequately reflected in the CEA. This tends to support the view of the Washington Panel that indirect costs (productivity costs) be measured through quality of life in the denominator of the CEA ratio and challenges the very basis of including indirect costs in economic evaluation.

Furthermore, it is not clear whether the argument made for QALYs — mostly used in developed countries — is relevant in developing countries where the use of DALYs is common.

Williams (1992) argued that, due to information problems about indirect costs, these could be ignored. He also argued that the inclusion of such costs would lead to ethical problems by favouring those in active service against retirees and the handicapped. The main contradiction in Williams is that, although he implies the inclusion of indirect costs in economic evaluation might change some of the rankings in the cost per QALY league tables and influence the conclusions of CEA, he also states they should be ignored due to information problems. Olsen and Richardson (1999) suggested that including indirect costs may lead to what they refer to as "unacceptable distributional consequences". However, they were not very clear as to what those consequences are.

The position of guidelines for economic evaluation relating to the inclusion of indirect costs in economic evaluation varies. Whilst the Finnish, Portuguese and Dutch have been very unambiguous about the inclusion of indirect costs (Finnish Ministry of Social Affairs and Health, 1999; Hjelmgren et al, 2001; INFARMED, 1998), the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom has limited itself to including 'net service and other costs' (NICE, 2001). The guidelines for England and Wales call for full opportunity costs to be included but are not clear about what is meant by full costs (Jacobs et al, 1995; Hjelmgren et al, 2001). The Canadian guidelines also call for all costs to be included but are not clear about patients' costs (CCOHTA, 1997). The Ontario guidelines request the inclusion of all relevant health care costs (Ontario Ministry of Health, 1994). Publication guidelines for the British Medical Journal (BMJ) and the Journal of the American Medical Association (JAMA) request that resource use costs associated with the intervention be included (Drummond and Jefferson, 1996; FDA, 1995; Siegel et al, 1997). It therefore seems that the decision to include indirect costs depends on the objectives of the evaluation, the geographical setting of the intervention and the perspective chosen.

Rutabanzibwa-Ngajza et al, (1985) have emphasised the importance of the contribution to the agricultural sector by rural women in developing countries, but little has been done to assess the effect of unpaid household work on health interventions in subsistence settings.

According to Anker in his editorial to Goldschmidt-Clermont (1987), due to the low labour productivity of household activities, women in developing countries devote long hours to back-breaking work each day, and there are few days, if any, which do not require these tasks to be performed. This leaves little or no time for other activities outside the household. Therefore, for women predominantly involved in subsistence work, the inclusion of indirect costs in the evaluation of interventions affecting them is likely to be important. Most people in developed economies engaged in paid work may not lose wages for short-term utilisation of health services (Torgerson et al, 1994; Law, 1995). Furthermore, such people may have sufficient funds to afford the extra-costs of getting care by foregoing work. By contrast, it is the informal sector that dominates the economy in developing countries, rather than the formal sector especially in rural areas.

The informal sector is deemed conceptually, methodologically and theoretically difficult to define in terms of its nature, size and importance, leading to criticism of lack of clarity (Peattie 1987; Bromley 1990). However, the definition that fits its use in this thesis is that it describes economic activity that takes place outside the formal norms of economic transactions established by the state and formal business practices (Cross, 1998). The informal sector represents a big component of economic activity, particularly in developing countries where it provides economic opportunities for women and the poor (Cross, 1998). The formal sector is the inverse of the informal sector as it mainly describes economic activity that takes place within the relatively structured economic transactions established by the state and formal business practices. Movement between formal and informal sectors, especially in remote rural areas, is almost non-existent, thus leaving people with no other choice but to work within the informal sector. Work in rural areas of developing countries is characterised by unpaid household chores and subsistence work (including farming and gardening).

Furthermore, people in developing country settings use time-consuming travel modes such as public transport and walking, and are usually accompanied by caregivers (Torgerson et al, 1994). Time may be so precious to these rural women that it may affect their health-seeking behaviour, thereby reducing the effectiveness of interventions that benefit them (Clarke et al, 2000). The effects of these time costs tend to be more evident in the case of preventive care than for treatment (Kutzin, 1993). Unlike illness, which may result in pain and suffering that can compel the sufferers to seek treatment, prevention rarely involves such discomfort and so people may not see the urgency to seek care (Ratcliffe, 1993).

Indirect costs are especially difficult to assess in a subsistence setting such as The Gambia and are therefore often excluded in economic evaluation. The few studies in developing countries that have looked at the household costs of health care have used different methods of calculation. In their attempt to summarise the various methods used to value indirect costs in developing countries, Attanayake et al (2000) found that mean daily income (Sharman et al 1990), average wages (Sawyer et al 1993; Jayawardane 1993; Asenso-Okyere and Dzator 1997; Konradsen et al 1999), daily output per adult (Shepard et al 1991; Sauerborn et al 1991) and average income per day (Ettling et al 1994) were the most popular methods. Attanayake et al used the output-related method to measure indirect costs, by relating loss of time with loss of output at individual and household levels, but they failed to consider household chores. The only time use study at household level in The Gambia that had the potential to include indirect costs was conducted by Aikins (1995) using the technique of Random Spot Observation. However, the findings were not integrated into an economic analysis.

The multiple roles of women in rural settings, which include being utilisers of maternal and MCH services and traditional care, providers of informal care, child bearing, producers of food and also less commonly wage labour (Rutabanzibwa-Ngajza et al, 1985), make utilisation of antenatal care a potentially time-consuming activity for them. Domestic activities are exclusively performed by unpaid household members, and in the case of The Gambia, by women. An important component of a women's life in The Gambia is devoted to unpaid work. Unpaid work includes household work, farming during the rainy season, gardening during the dry season and petty trading all year round in rural towns. Time is of fundamental importance for the women particularly during the rice-planting season when rest and leisure are usually cut to a minimum and attendance at clinics is greatly reduced (Rutabanzibwa-Ngajza et al, 1985).

In The Gambia, all pregnant women pay registration fees of five Gambian Dalasis (US$0.25) to obtain a client-held antenatal care record card. This card entitles the holder (pregnant woman) to free consultations and medication during pregnancy and until six weeks after delivery for all conditions related to the pregnancy. Despite this relatively minimal financial cost, the average national antenatal visit rate is just 3.4 times per woman (Cham, 2003), which falls below the WHO-recommended target of four (WHO, 2001). The rate is lower in rural areas where women are sometimes prepared to incur extra financial costs by buying medication at local drug stores instead of visiting designated antenatal clinics (Cham, 2003). One of the reasons for this, according to Cham (2003), is to circumvent the opportunity cost of time related to receiving health care at the facility level.

A study by Francis Foord in 2000 suggested that, by following the historical pattern of restricting MCH services to facilities in catchment areas, the vast number of potential beneficiaries might not fully utilise the services. Furthermore, staff attitudes and poor organisation of tasks at clinics cause patients and their caregivers to spend long periods waiting before receiving care (DoSH, 2000). These factors are likely to elevate indirect costs and undermine the uptake of SP as IPTp.

The WHO's recommendation of using antenatal clinics as centres to provide IPTp with SP (WHO, 2002), should not be embraced blindly but in accordance with the characteristics of the setting where the intervention takes place. It is likely that interventions may suffer from lack of subjects in areas where clinic attendance is not regular and falls short of the required number of times for SP to be efficacious (at least two doses). This underscores the fact that for interventions such as IPTp with SP to succeed in The Gambia, allowance for indirect costs is likely to be critical because of the time-cost involved in getting the participation of patients, their families and caregivers in the programme.

1.2 OBJECTIVES AND CONTENT OF THESIS

The above text has identified a lack of knowledge on the cost-effectiveness of IPTp for multigravidae, and a lack of attention paid to a potentially important element of CEA, namely indirect costs. This thesis therefore has three main objectives. First, to examine the cost-effectiveness of introducing SP as IPTp for malaria into normal antenatal care for multigravidae women in rural Gambia, second, to explore various methods of valuing indirect costs and assess the extent to which they affect the cost-effectiveness ratio; and third, to make policy recommendations as to whether to introduce SP as IPTp on cost-effectiveness grounds.

The thesis is presented in 11 chapters. This chapter has presented the statement of the problem and rationale for the study. Chapter 2 reviews the existing literature on economic evaluation including the basic techniques of economic evaluation. It also reviews the approaches of measuring and valuing unpaid work, and the empirical literature on the measurement of indirect costs in economic evaluation with special emphasis on unpaid household work. Finally, gaps in the current literature are identified. Chapter 3 reviews the literature on malaria in pregnancy in developing countries. It first reviews the general literature in SSA, focussing on the prevalence of low birth weight (LBW) categorised as extremely low birth weight (ELBW), very low birth weight (VLBW) and low birth weight (LBW), and in terms of very severe anaemia, severe anaemia and moderate anaemia.

Strategies for the prevention and control of malaria in pregnancy in Sub-Saharan Africa in general, and specifically within the context of The Gambia, are presented in the same chapter. The chapter concludes with an overview of economic evaluations of malaria in pregnancy in SSA. Chapter 4 describes the study setting. This chapter presents information on the geographical, climatic, demographic and economic situation of The Gambia. This includes the poverty and gender situation of the country with emphasis on the effects on women and their health status.

Chapter 5 describes the relationship between the cost-effectiveness study and the IPTp trial. It also expands on the objectives of the empirical part of the thesis. The conceptual framework used for the analysis of costs and consequences data, how to move from efficacy to effectiveness, and trial/research and protocol driven costs are presented in this chapter. This is followed by a description of the methods used in the study including piloting, sampling, data collection tools and the various methods of data collection. Next, the data analysis plan is presented, which includes the various methods of valuing time, health consequences, cost-effectiveness analysis and incremental cost-effectiveness ratio (ICER) and sensitivity analyses. Chapter 6 presents the background characteristics of the study subjects and their households. It goes on to present the results of IPTp costs to the health care provider as well as the direct costs to women and their relatives. The direct costs of treatment for LBW and anaemia to the provider, patients and their families at the Armed Forces Provisional Ruling Council Hospital (AFPRCH) and Royal Victoria Teaching Hospital (RVTH) are presented.

Chapter 7 presents the results of the household time use study in terms of the main activities, which are used to estimate the indirect costs of IPTp intervention, LBW and anaemia treatments. It estimates the hourly wage rate for women for various household tasks and selected wage rates for men in the study setting. Four different approaches are used to value time. These are later used to estimate the indirect costs of the IPTp intervention as well as the indirect costs of LBW babies and anaemic mothers. The indirect costs of treating anaemia at AFPRCH and LBW and anaemia at RVTH are also presented in this chapter.

Chapter 8 presents the effectiveness results in terms of health outcomes and resource savings to the provider, patients and their families. Health outcome measures include malaria cases averted, deaths averted, Disability Adjusted Life Years (DALYs) averted for the three categories of caring for LBW (i.e. LBW, VLBW and ELBW) and the three types of anaemia (i.e. anaemia, severe anaemia and very severe anaemia). This is done in two phases, Base cases I and II.

Base case I uses the multigravidae population in the study site and Base case II uses the multigravidae population in the trial site who do not sleep under bednets. Chapter 9 presents the results of the incremental costs and consequences of IPTp in terms of Base cases I and II. A detailed sensitivity analysis is also included in Chapter 9. Chapter 10 goes on to discuss the methodological shortcomings of the study and summarises the main findings of the research in relation to the study objectives. It also discusses the findings and compares them with other malaria control interventions conducted both nationally and internationally. Chapter 11 draws conclusions and discusses the policy implications with respect to the major study findings. Furthermore, it identifies gaps that may need to be filled by future studies. Appendices contain questionnaires, operation manuals and detailed calculations.

CHAPTER 2: REVIEW OF THE THEORETICAL AND EMPIRICAL LITERATURE

2.1 INTRODUCTION

Due to the scope of the literature, this review chapter is divided into six sections. Section 2.2 outlines the basic forms of economic evaluation; Section 2.3 assesses approaches to valuing indirect costs in economic evaluation; Section 2.4 looks at the features of subsistence economies and the importance of indirect costs to these economies; and Section 2.5 reviews empirical methods used to measure and value indirect costs. In Section 2.6, the empirical literature on the economic evaluation of preventive health care, with particular emphasis on indirect costs especially unpaid work was conducted. The same section summarises the gaps in the existing literature. A summary of the whole chapter is given in Section 2.7.

2.2. OUTLINE OF THE BASIC FORMS OF ECONOMIC EVALUATION

All resources are scarce and the aim of economics is to maximise benefits from these limited resources through priority setting by allocating them in an efficient manner (Slothuus, 2000), hence the need for economic evaluation. Economic evaluation identifies and makes a set of criteria, which may be useful in deciding alternative uses of limited resources. According to Mills and Gilson (1988), the techniques of economic evaluation play a significant role in the methods of health service evaluation and are based on the concern economists have with economic efficiency and opportunity cost. Drummond et al (2005) define economic evaluation as "*the comparative analysis of alternative courses of action in terms of both their costs and consequences*". The basic task of economic evaluation includes the identification, measurement, valuation, and comparison of costs and consequences of the competing alternatives being considered.

In the definition, "alternative courses of actions" are assessed in terms of both costs and consequences. "Consequences" are the collective term for the results of an intervention and depend on the techniques of analysis used (Drummond et al, 2005). The differences in techniques lie in how to deal with the identification, measurement and valuation of costs and consequences and on the objective and perspective of the evaluation. Economic evaluation may be conducted from health service, third-party payer, patients and societal perspectives (Coast et al, 1996). Coast and colleagues went on to indicate that, the costs considered from the perspectives of the health services or third party payers usually focus on the direct costs of providing different treatments including drugs and the effects of these drugs on associated treatment.

Out-of-pocket and travel costs of patients are taken into account when the patient perspective is taken. Finally, societal perspective takes into account all the costs mentioned earlier and indirect costs associated with the time lost from work through mortality or morbidity resulting from treatment (Coast et al, 1996). Although there are several forms of economic evaluation, only those that examine both costs and consequences for two or more alternatives are regarded as full economic evaluations (Drummond et al, 2005). These are Cost-effectiveness analysis (CEA), Cost-utility analysis (CUA) and Cost-benefit analysis (CBA) (see Figure 2.1). Cost-minimisation analysis (CMA), used when two interventions have the same consequences and the decision rule is to establish the least cost alternative, is not strictly classified as full economic evaluation (Drummond et al, 2005).

Figure 2.1 Distinguishing characteristics of health care evaluation

Are both cots (inputs) and consequences (outputs) of the alternatives examined?

		No		**Yes**
Is there Comparison of two or more alternatives?	**No**	Examines only consequences	Examines only costs	
		1A. Partial evaluation	**1B**	**2. Partial evaluation**
		Outcome description	Cost description	Cost-outcome description
	Yes	**3A. Partial evaluation**	**3B**	**4. Full economic evaluation**
		Efficacy or effectiveness evaluation	Cost analysis	Cost-effectiveness analysis Cost-utility analysis Cost-benefit analysis

Source: Drummond et al (2005)

Figure 2.1 Distinguishing characteristics of health care evaluation

2.2.1 Cost-effectiveness analysis (CEA)

CEA compares two or more interventions, measuring costs in monetary terms and outcomes in common units such as the number of cases or deaths averted, Disability-Adjusted Life Years (DALYs) averted, which may be achieved to different degrees by the alternatiyes. The decision rule is to find the lowest cost per unit of consequence. CEA is used mostly in situations where a decision-maker operating with a given budget is considering a limited range of options within a given field (Drummond et al, 2005; Witter, 2000).

The DALY is a measure of the burden of disease that reflects the total amount of healthy life lost to all causes, whether from premature mortality or from some degree of disability (physical or mental) during a period of time (WDR, 1993). DALYs allow fatal and non-fatal outcomes to be combined into a composite estimate (Anand and Hanson 1997), which makes it possible for interventions to be ranked according to their cost-effectiveness. This, as noted by DFID (2000), overcomes the problems of other forms of economic analysis, which are either relevant only to specific diseases or rely on placing monetary values on lives. According to Murray (1996), Murray and Lopez (1997); and Murray and Acharya, (1997), the intended use of the DALY is to assist in:

1. Setting health service priorities;
2. Setting health research priorities;
3. Identifying disadvantaged groups and targeting of health interventions and
4. Providing a comparable measure of output for interventions, programmes and sector evaluation and planning.

Specifically, the DALY is the sum of the present value of future years of lifetime lost through premature mortality, and the present value of years of future lifetime adjusted for average severity, frequency and intensity of any mental or physical disability caused by disease or injury (Fox-Rushby and Hanson 2001). It is an indicator of the burden of disease, which is the sum of the years of life lost (YLL), and years lived with disability (YLD). The usual definition of YLL is the difference between age at death and life expectancy for each age, and YLD is the number of years lost from varying degrees of disability associated with diseases (Brenzel, 1993). Brenzel further argues that, as a composite indicator, using the DALY is intuitively appealing in that it incorporates morbidity-adjusted years of life lost, and therefore, provides a better picture of the total burden of diseases in a society. Furthermore, being able to disaggregate DALYs by gender and even by age provides additional information from which health policy and resource allocation decisions can be made.

In CEA, one assumes that the objective is desirable even though benefits cannot be evaluated in monetary terms (Folland et al, 2001). CEA avoids the problem of valuation of health outcomes, which makes it preferable to cost-benefit analysis (Warner and Hutton, 1980). CEA is a flexible technique as it permits comparison between interventions targeted to the same disease, or compares interventions targeted at different diseases depending on the chosen outcome measure.

Despite these advantages, CEA has its limitations too. The first of these is that it is not designed to determine the value of a programme to the society, nor does it permit comparison of interventions with different impacts on morbidity and mortality (Evans and Hurley, 1995). Furthermore, cost-effectiveness ratios are specific to a particular group of patients or settings and are affected by prevalence of the disease, scale of operation and technological advances (Neumann and Johannesson, 1994). There are disagreements over some CEA methodologies such as the appropriate discount rate to use and whether or not to include productivity gains or losses. Inclusion of productivity gains or losses either as costs or consequences is contentious and controversial (Drummond et al, 2005; Weinstein, 1995) and was highlighted in Chapter 1.

Health state valuations have their shortcomings. However, for the purpose of this thesis, which used DALYs as the outcome measure, concentration is on critique of DALYs with emphasis on their construction and application. The critique draws on a number of recent reviews of DALYs (Fox-Rushby, 2002; DFID, 2000; Anand and Hanson, 1997) but the focus is on those attributes likely to affect the results of this study directly. Firstly, DALY estimates are based on data that do not include socio-economic or environmental factors or measures of unmet health needs (Arnesen and Kapiriri, 2004), and the process of determining preference weights has been described as unrepresentative and not transparent (Paalman et al, 1998). Age-weighting means that life years are assigned different values at different ages (Arsene and Kapiriri, 2004) with an emphasis on working adults aged between 20-30 years (DFID, 2000; Anand and Hanson, 1997). Some age weightings are considered inappropriate. For example, the age weighting given for anaemia is zero (Arnesen and Kapiriri, 2004). Secondly, there is no consensus on whether to use a discount rate and if one is to be used, then at what rate. The use of a discount rate values future years of life lived less than present years, which, according to Anand and Hanson (1997), can only be justified based on environmental degradation, which tends to benefit the present generation. Thirdly, the effects of illness are captured through six disability classes, which assign increasing disability weights associated with the extent of loss of physical functioning (Murray, 1994, p439), chosen by a group of experts.

The weights given would therefore depend on the questions posed to the experts and their responses based on their understanding of the use of estimates (Barker and Green, 1996; Anand and Hanson, 1997). Furthermore, using 'experts' can lead to;

1. Lack of unbiased judgement;
2. Not reflecting social preferences;
3. Not taking patients' perceptions into account;
4. Lack of personal experience and
5. Variation of values from expert to expert (DFID, 2000; Paalman et al 1998; Barker and Green, 1996; Anand and Hanson, 1997).

Barker and Green (1996) specifically asked who the experts were and questioned their representativeness in terms of gender and social class. To overcome some of the shortcomings of CEA related to outcome measurement, Cost-utility analysis (CUA) is used.

2.2.2 Cost-utility analysis

CUA is a form of economic evaluation that compares two or more interventions, measuring inputs in monetary terms and outcomes in a measure of improved utility. The most well-known measure of outcome for CUA is Quality of Life Years (QALYs) (Tan-Torres Edejer et al 2003). According to Williams (1985), QALYs are developed to unify scale of value for life and health, death and disability that may be used to measure the outcome of health care. QALYs are estimated by adjusting the length of time affected through the health outcome by the utility value (on a scale of 0 to 1) of the resulting level of health state (Drummond et al, 2005). QALY league tables guide decisions about incremental costs and benefits by setting reference points or thresholds (Mooney, 1989). The optimal decision criterion involves ranking the incremental cost-utility ratios of competing interventions and choosing those with the lowest price per QALY until the budget is exhausted (Palmer et al, 1999; Rawles, 1989). Other potential outcome measures are Saved-Young-Life Equivalents (SAVE) (Nord, 1995), Health Years Equivalents (HYE) (Mehrez and Gafni, 1989), etc.

Despite improving on some of the shortcomings of CEA, CUA has its own limitations. One of these relates to measurement of outcome by utility, which is relatively young and the methodologies are still under development (Torrance, 1987). For example, individual preferences for alternative health states can be collected from survey of patients, the general public or health care providers. It is likely that patients who are familiar with pain and suffering of diseases may weigh alternative health states differently than the general population. Doubts have also been expressed about the theoretical background of CUA.

According to Slothuus (2000), QALYs are measures of preferences for health status and not welfare and therefore concentration is on improvements of QALYs. There also exist difficulties in obtaining adequate information on the costs and consequences of all the competing interventions required for the ranking (Palmer et al, 1999).

2.2.3 Cost-benefit analysis (CBA)

The third form of full economic evaluation is CBA. CBA entails measuring and valuing costs and benefits of alternative programmes in monetary terms and comparing them in order to assess which ones are desirable using decision criteria (Klarman, 1967). The monetary benefits and costs for each time must be estimated and then discounted back to the present time. The fundamental rationale behind CBA reflects the need to determine an efficient allocation of resources when an underlying market is not readily available (Folland et al, 2001). The costs consist of programme expenditures and the benefits comprise averted future losses with the success of the programme. Klarman (1967) identifies three groups of benefit as savings in the use of health care, gains in economic output and satisfactions from better health. The outcome of CBA is expressed in monetary units with total costs compared with total benefits.

One of the disadvantages of CBA is its valuation problems with respect to valuing benefits. The two well-know valuation methods are the Human Capital Approach (HCA) and Willingness To Pay (WTP) approaches. The HCA values the economic return (benefits) to society using individual's expected earnings (annual income). This invariably lowers the value of life of individuals outside formal employment (i.e. elderly and children) and in developing countries where wages are low (Creese and Henderson, 1980). The WTP approach is based on the potential Pareto improvements, i.e. gainers from an intervention could compensate losers and still be better off. This is used as a criterion to judge whether a programme is desirable (Cullis and West, 1979; Mills and Thomas, 1984 and Drummond et al, 1987). The decision criterion is that a programme will be given the go-ahead if the benefits exceed the costs. CBA techniques are developed from welfare economic theory making use of potential Pareto improvement criterion to maximise the welfare of the community. It requires that the benefits be enough for the beneficiaries to, — in theory, — compensate the losers. The Pareto optimal position implies technical and allocative efficiency in terms of consumption and production efficiency whereby the marginal rates of substitution in consumption and production are equal (Dinwiddy and Teal, 1996).

Efficiency and forms of Economic Evaluation

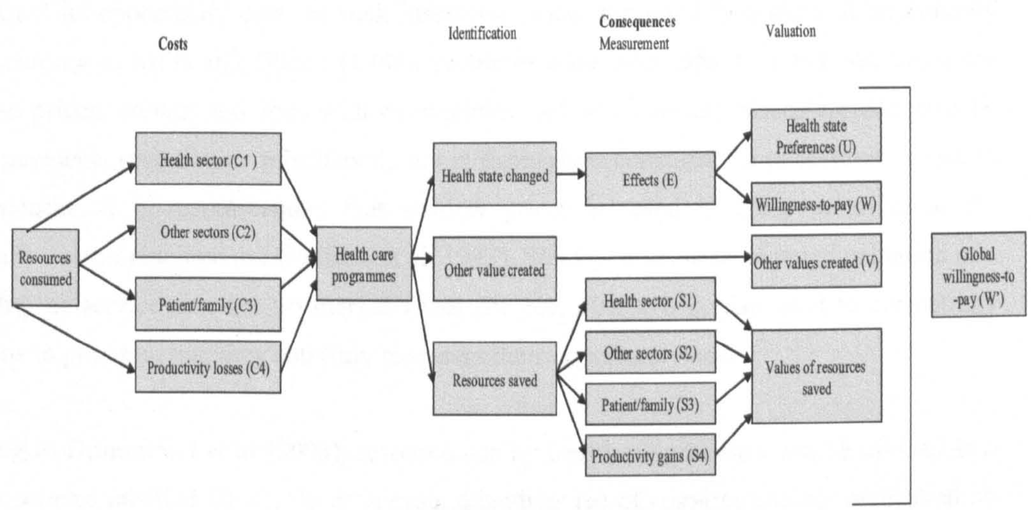
Efficiency in economic evaluation is divided into what is referred to as Technical and Allocative efficiency. Technical efficiency arises when a minimum combination of inputs are used to produce a given level of output (Nicholson, 2000; McGuire et al, 1988). In health care, technical efficiency is achieved where utilisation of resources produces a level of benefit that cannot be exceeded by utilising the same resources in an alternative way. In that case, productive efficiency, which is the maximisation of health outcome for a given cost, or the minimisation of cost for a given outcome is applicable (Barnum, 1993; McGuire et al 1988). Allocative efficiency is achieved when a given quantity of goods produced over a period is allocated among consumers in a way that makes it impossible to make someone better off without making another worse-off (Clewer and Perkins, 1998). Allocative efficiency takes into account the production efficiency with which health care resources are used to produce health outcomes as well as the way in which these outcomes are allocated among individuals in society. In summary, technical efficiency addresses the issue of using given resources to maximum advantage; production efficiency addresses the issue of choosing different combinations of resources to achieve the maximum health benefit for a given cost; and allocative efficiency focuses on achieving the right mixture of health care programmes to maximise the health and welfare of society (Slothuus, 2000). In CEA/CUA, only productive efficiency is used with outcomes restricted to health benefits because it is not possible to use technical efficiency to compare alternative interventions where one intervention produces the same or better health outcome with less or more of one resource and more or less of another (Slothuus, 2000). According to Cam Donaldson et al (2002), CEA alone cannot handle questions of allocative efficiency despite the expectations that it could do so. In contrast, CBA, which is broader in scope is able to inform questions of allocative efficiency because it can assign relative values to both health and non-health related goals to determine which goals are worth achieving, given the alternative uses of resources and thereby determining which programmes are worthwhile (Drummond et al, 2005).

2.2.4 Relevant costs and consequences in economic evaluation of health care programmes

The previous section shows the different types of economic evaluation, each measuring and valuing the various costs and consequences to different extents. Theoretically, there are three main perspectives on the role of economic evaluation in health care such as the welfarist (Birch and Gafni, 1996); the extra-welfarist (Culyer, 1989) and the decision-maker approach (Sugden and Williams, 1979).

Drummond et al (2005) acknowledged that, due to these differences in perspectives on economic evaluation, it is useful to view the various costs and consequences of health care programmes as building blocks that can be assembled in different ways. The detailed breakdown of these costs and consequences are shown in Figure 2.2.

Figure 2.2 Components of economic evaluation in health care



Source: Drummond et al (2005)

Figure 2. 2 Components of economic evaluation in health care

Costs

Costs are considered both in financial and economic terms. Financial costs are the expenditure on goods and services including health care. Direct costs to patients consist of monetary expenses in terms of fares paid, out-of-pocket expenses, user fees for outpatient visits and bed fees for those admitted. Costs in economics are regarded as the opportunity cost of resources used in an intervention; defined as the value of the benefits foregone in the next best alternative use (Drummond et al, 2005). In efficient markets, the value of any resource (market price) would equal its opportunity cost. In such instances, prices are good indicators of opportunity cost. According to Mills and Gilson (1988), problems arise over gifts or donations; resources with false prices; certain activities with externalities and when money prices are distorted by transfer payments (taxation or subsidies do not in themselves constitute an opportunity cost). In such instances, it is recommended that shadow prices be used in order to arrive at the opportunity cost of resource use (Phillips et al, 1993). Shadow price is an imputed valuation of a commodity or service that has no market value (Pearce, 1992). It is also used to correct any distortions in prices so that they can truly represent their opportunity costs.

According to Drummond et al (2005), resource use by health programmes can be divided into four components labelled C_1- C_4. In each case, quantities (q) of resource use are multiplied by their respective prices (p) to arrive at these costs. C_1 refers to the costs of resources used in an intervention, including resources used in dealing with any possible adverse effects. They include drugs, equipment, hospitalisation, physician visits etc. This also comprises the costs of providing the initial intervention and costs of treatment. The common method of identifying these resources is known as the "ingredients approach'', which may include both variable and fixed costs. The ingredients approach is a method where the values of inputs are based on quantities and unit prices (WHO, 2006).

C_2 refers to the resources consumed in other sectors and depends on the nature of the health care interventions being evaluated. i.e. whether they rely on resources from other public sectors (Drummond et al, 2005). C_3 is the patient and family resources, which may consist of direct costs such out-of-pocket expenditures accruing from fares to travel to the health facilities, user-fees, other payments, informal care cost at home, expenses incurred by patients or family members and the value of any resources that contribute to the treatment process. Furthermore, patients and their families use time during treatment. This could be the time spent by patients and their family caregivers in seeking and receiving care at health facilities and at home. The valuation of these times has been a subject of controversy and will be discussed in detail in Section 2.3.

C_4 is the productivity loss associated with the time spent by patients and their families in seeking treatment. These productivity losses to patients and their families were originally referred to as indirect costs. Productivity gains occur when a health intervention free up time for patients and their families.

Consequences

Another requirement for a full economic evaluation is the identification of the consequences (or effects) that need to be measured and valued. Consequences (or effects) consist of the therapeutic outcomes or effects of the alternatives being compared (Drummond et al, 2005, Drummond et al, 1987, Drummond and Stoddart, 1985). The first category of consequences are: change in patients health state, which can be measured in terms of effects (E); life years gained or disability days reduced. This can also be valued in terms of health state preferences (U) in the case of CUA or in terms of WTP for CBA.

The second value (V) can result from the health intervention but not necessarily linked to the improvement in health state. This is usually referred to as the process utility (Donaldson and Shackley, 1997). Process utility includes the value of information or reassurance about one's health state. The third is based on the premise that health care intervention can save resources and these savings range from S_1 to S_4. The savings (S_1-S_4) are said to mirror C_1 to C_4 discussed earlier and are measured in a similar way. These savings are regarded as the costs not spent on the alternative programme. According to Mills (1989), cost-effectiveness studies do not only divide programme costs by health effects (consequences) but they are increasingly netting out savings in treatment costs and the value of indirect benefits (savings in work time) from programme costs. Finally, the Global Willingness-to-pay (W') for the programme may be ascertained. This valuation can potentially include all the consequences identified in Figure 2.2, depending on what the respondent(s) to the WTP perceives to be important (Drummond et al, 2005). The different forms of economic evaluation have been expressed by Drummond et al in equations 1-3 below with the details in the text.

Cost-effectiveness analysis = $(C_1 - S_1)/E$

$\{(C_1 + C_2 + C_3 + C_4) - (S_1 + S_2 + S_3 + S_4))/E$ Equation......... (1)

Where: C_1...C4 represent costs

S_1- S_4 represent savings
E - represents effectiveness

Cost-utility analysis = $(C_1 - S_1)/U$

$\{(C_1 + C_2 + C3 + C_4) - (S_1 + S_2 + S_3 + S_4))/U$ Equation......... (2)

Where: U represents health state preference and the Cs are as illustrated in equation (1)

Cost-benefit analysis = $W' - (C_1 + C_2 + C_3 + C_4)$

$((W + V + S_1 + S_2 + S_3 + S_4) - (C_1 + C_2 + C_3 + C_4))$ Equation .... (3)

Where: V represents process utility

W represents Willingness To Pay and Cs are as described in equations (1) and (2).

Drummond et al (2005) argued that the inclusion and exclusion of costs and consequences of the health care interventions in economic evaluation should be "judged in the larger context of objectives for health services in a given country". According to Drummond and colleagues, despite the difficulty involved, the full identification of all costs and consequences was necessary for researchers to make the appropriate informed decision on whether to consider indirect costs or not (Drummond et al, 2005, Coast et al, 1996; Drummond and Stoddart, 1985). They recommended that, after identifying all the likely costs and consequences of the health care interventions through situation analysis, those small ones – costs and consequences – not worth calculating should be discarded from the analysis (Coast et al 1996). According to Drummond et al (2005), indirect costs arising from patients or family members, taking time off work to receive health care may not be substantial in practice because patients may already be out of work due to poor health or they may be elderly persons beyond the age of any full-time employment. However, indirect costs could be higher in the case of certain types of health intervention such as screening or therapeutic interventions that enable the early return of patients and informal family carers to work and/or even prolong their working lives in case of life saving treatments (Drummond et al, 2005).

2.3. VALUING INDIRECT COSTS IN ECONOMIC EVALUATION

2.3.1. Introduction

This section critically assesses the different approaches to valuing indirect costs (productivity loss). Three distinct but not wholly mutually exclusive approaches of valuing indirect costs are the Human Capital Approach (HCA), Friction Cost Approach (FCA) and Washington Panel (US Panel) Approach (WPA).

2.3.2. Human Capital Approach (HCA)

The HCA estimates the potential value of lost production (Grossman, 1972; 1999). According to Grossman (1972; 1999), the term human capital was first discussed by Pigou (1928) who stated that there was investment in human capital as well as investment in material capital. However, the use of human capital in modern neo-classical literature dates back to Jacob Mincer's article titled: '*Investment in human capital and personal income distribution*' (*The Journal of Political Economy*, 1958). Gary Becker's book titled *Human Capital*, published in 1964, became the standard reference for many years. According to Becker, human capital is similar to physical means of production such as factors and machines. One can therefore invest in human capital via education, training, medical treatment and one's income depends partly on the rate of return on the human capital. On the other hand, Grossman's approach to the demand for health care (the human capital model) states that an increase in a person's stock of knowledge or human capital raises his/her productivity in the market sector of the economy where he/she produces money earnings, and in the non-market or household sector, where the person produces commodities that enter his/her utility function (Grossman, 1972). To realise potential gains in productivity, individuals have an incentive to invest in formal schooling and on-the-job training. The costs of these include direct outlays on market goods and the opportunity cost of the time that must be withdrawn from competing uses. Grossman acknowledged Mushkin (1962), Becker (1964), and Funch (1966) as earlier authors on the importance of health human capital. In 1972, Grossman constructed a model of the demand for health capital by using the household production model of consumer behaviour (Grossman, 1999). Grossman's approach draws on Becker, 1964; Lancaster, 1966 to account for the gap between health as an output and medical care as one of many inputs into production. Grossman argues that a person's stock of knowledge affects the market and non-market productivity, while the stock of health determines the total amount of time spent producing money earnings and commodities (Grossman, 1972).

The human capital approach to valuing indirect costs is defined as, 'the potential gross earnings lost during the time a sick person is absent from work' (Johannesson, 1997; Weisbrod, 1969; Rice and Cooper, 1967); counting from the first day the person is absent due to illness to the time of retirement in the case of permanent disability or death. The HCA assesses the impact of health care on lost work time, whether through prevention of illness or death for the individual undergoing treatment (Pritchard and Sculpher, 2000). Lost productivity due to the impact of morbidity and mortality on paid work are the present value of lost gross wages over the period of illness and from time of death to retirement respectively (Pritchard and Sculpher, 2000). HCA also uses the gross wage rate earned by individuals undertaking similar work on a paid basis to value lost time from unpaid work (Liljas, 1998; Luce et al, 1996). This gives room for the time used by unpaid caregivers to be valued. Aggregation of those individual figures yields productivity costs at the national or intervention level.

The argument for using the gross wage rate to value lost production is based on the neo-classical viewpoint that wage rates are the equivalent of the value of marginal productivity (Johannesson, 1997). Therefore, all earned income can be taken as the monetary value of production lost. Work time is valued according to gross wage in the sense that, in a well-functioning labour market, productive output and the compensation to the worker are equal, because they represent the same resources (Weinstein et al, 1997). According to this theory, assuming diminishing marginal productivity, a profit maximising firm would employ additional labour until the marginal product of the last unit of employment cost faced by the firm equals the wage. The latter is the gross wage including additional costs of employment such as employer's contribution to insurance (Pritchard and Sculpher, 2000). This is what forms the basis of using the gross wage as the value of lost production during absence from work.

The approach values the allocation of time both in market and non-market work. The measurement of unpaid work requires imputing an equivalent value for those not in paid employment using a number of methods (Drummond et al, 2005). These include the use of average wages, the cost of replacing individuals, or the opportunity cost of the production they could have contributed were they not at home (see Section 2.5.3; especially 2.5.3.1 for details). By using the human capital approach, productivity benefits in earlier studies were usually estimated based on the additional stream of lifetime income for an individual because of a given health care programme (Rice and Cooper, 1967).

According to Mishan (1971), the main criticism of the human capital approach is its link to welfare economic theory and the implicit assumption that the objective of health care was to maximise national productivity. HCA's assumption of full employment is also said to be unrealistic. Although in theory wage rates reflect marginal productivity of a worker, due to inherent imperfections in labour markets, wage rates may reflect inequities such as discrimination by race and gender (Drummond et al, 2005). For studies that take societal perspective, consideration is given to the valuation of healthy time gained which has no market value, leading to use of shadow prices and all their shortcomings (Drummond et al, 2005). The Erasmus group comprising Koopmanschap, Brouwer and Ineveld and others also questioned the welfare basis of human capital theory in terms of full employment (Koopmanschap et al, 1995). According to them, in contrast to the assumption of the human capital theory, in reality, employment differs across occupation but unemployment occurs in all economies. HCA provides estimates of potential loss production because of disease, rather than loss that will be experienced in practice (Koopmanshap and van Ineveld, 1992). Koopmanschap and van Ineveld (1992) argued that in practice, compensating factors exist for absence from work due to mortality and morbidity, and organisations adjust to minimise the impact of the production losses. They acknowledged that production losses do occur but are usually limited to the period required to replace the worker. In addition, the human capital approach values benefits to society using the individual's potential annual income. This tends to undervalue the lives of people outside formal employment or where such employment opportunities and wages are low, as is the case in developing countries (Creese and Henderson, 1980). The Erasmus group came up with an alternative called the Friction Cost Approach (FCA).

2.3.3. Friction cost approach (FCA)

The FCA of valuing indirect costs was put forward by the Erasmus group as an alternative to the HCA (Brouwer and Koopmanschap, 2005). The group assumed that workforce conditions were such that unemployment was at levels higher than the frictional level of unemployment and that there was a possibility of replacing long-term absentees from work. The frictional unemployment period is the time taken before a position is filled. In that case, the society will restore initial levels of production after a period of adaptation, the duration of which depends on the level of unemployment (Brouwer and Koopmanschap, 2005).

If unemployment is greater than the frictional unemployment level, it should be possible to replace an employee because of illness or disability after a period (Koopmanschap et al, 1995; Koopmanschap and van Ineveld, 1992; Koopmanschap and Rutten, 1993; Koopmanschap et al, 1995).

The FCA is based on the notion that the amount of production costs depends on the time that organisations need to restore the initial production level (Koopmanshap and Rutten, 1996). The focus of the FCA was initially on valuation of lost time from paid work with unpaid work valued at zero. However, in a recent article by Jacob-Tacken et al (2005), the use of the patient's wage to measure short-term absence from work was questioned on the basis that such time is compensated for during normal work hours and therefore does not lead to productivity losses. They argued that, in such cases, the use of the wage rate tends to overestimate productivity costs. When they examined the productivity costs for five patient populations and one employee population using the classical method of identifying when extra effort was needed, the findings showed that productivity costs based on identifying efforts were 25-30% of the classical estimates. For one-day absence, productivity costs were relevant in only 17%-19% of individuals and 35%-39% for two days or longer.

FCA values productivity under three scenarios. For temporal illness, lost productivity could be made up on return to work or by internal labour reserves with the impact limited to medium term macroeconomic effects. Alternatively, an increase in costs in the form of temporary workers or use of overtime can be approximated by the lost output of the sick person. In the case of short-term illness, the sick person on his or her return compensates for the lost time by cutting down on leisure and increasing work time, which has the same effect as if the firm had a pool of reserve workers who could readily replace sick employees (Brouwer et al, 1997). Although this still represents costs to the individual, the only cost to the firm in such a case is the medium term macroeconomic consequences of short-term absence. In the case of permanent/long term illness, workers experiencing illness or disability longer than the frictional period are replaced from the unemployed. For illness or disability longer than the frictional period, the productivity loss is valued as in the case of mortality (Brouwer et al, 1997). Productivity losses — and corresponding gains from health care — are limited to the frictional cost period and medium term macroeconomic effects. In the case of mortality, deceased workers are replaced from the unemployed with the same implications as for morbidity. Leisure is valued as the net take home wage. In the case of death, the lost productivity during the friction period is the time it takes to train and replace the deceased worker. However, the possibility exists for the deceased to be replaced within the firm, which further provokes a series of replacements within the firm until the last opened position is filled from outside.

Johannesson and Karlsson (1997) and Liljas (1998) criticise FCA insofar as it is based on strong assumptions not supported by neo-classical economic theory. For example, they especially criticised the FCA's treatment of mortality in that the absence of costs after the frictional cost period implied that the opportunity cost of labour was set at close to zero after the frictional cost period (Drummond and McGuire, 2001). They argued that a value close to zero of direct labour inputs would subsequently reduce the costs of health care interventions, which they considered unreasonable. The view that productivity loss could be compensated when the sick person returns to work, was countered on the basis that the output of the worker could not be equal to the gross wage he/she was paid. Otherwise, this theory defied an important economic principle of output being equal to the wage rate (Johannesson and Karlsson, 1997). Compensating lost productivity through overtime and reduced leisure time would also attract costs depending on the value people placed on their leisure. However, according to critics, FCA values leisure at zero.

If the marginal utility gain from leisure is higher than the wage paid, workers are likely to reject work in favour of leisure (Johannesson, 1997). Compensation through internal labour reserves means that firms are not operating at a profit-maximising level as stated in microeconomic theory. Internal labour reserves can only happen in very rare cases, in a labour market where recruitment is difficult. Furthermore, informal rather than formal work is the norm in many environments, especially in developing countries where the bulk of the people work at the subsistence level. FCA is difficult to operationalise, although some estimates have been made in the Netherlands and Canada (Koopmanschap et al, 1995; Koopmanschap and Rutten, 1996; Goeree et al, 1999).

It is difficult to estimate productivity losses for short-term illness or the person staying at home. It is hard to see why the frictional cost approach should not be applied to all resource changes. FCA implies a highly unrealistic scenario that unemployment could be solved if the number of hours worked by employed workers was reduced and the unemployed worked those hours instead. For periods of illness less than the frictional period, FCA estimated productivity costs at 80% of the value of production, which is inconsistent with economic theory (Johannesson and Karlsson, 1997).

2.3.4. Washington Panel Approach (WPA)

The most recent of the three approaches of valuing productivity costs stemmed from the recommendations of the Washington Panel on cost-effectiveness analysis for health care by Gold et al (1996). The Panel's definition of productivity cost can be divided into impaired role functioning and income reduction.

The Washington Panel recommend that analysts should make the choice to include productivity costs in the numerator or the denominator of cost-effectiveness ratios because, according to them, to include both quality of life effects of decreased productivity and all costs would lead to double counting. The preference of the panel as a 'reference case' is for productivity costs to be measured through quality of life in the denominator of the CEA ratio in terms of health effects, and any replacement costs in the numerator. The reason given is that substitute labour may not be as effective as what it replaces in terms of productivity. The Panel has linked quality of life to role functioning because of the belief that people tend to experience a higher quality of life at a time when they can function well in their social settings and also in their jobs, hence its incorporation into the denominator in the cost-effectiveness ratio (Weinstein et al, 1997) .

The time spent by patients participating in an intervention on activities such as travelling, waiting and the time spent receiving treatment represent a real change in the use of resources. Adjustments in treatment times are not a common practice in the measurement of health-related quality of life (Weinstein et al, 1997). They argue that failure to take those costs on board in any cost-effectiveness analysis would impair findings against interventions that relied on inputs or outputs that are purchased and in favour of those that rely on patients, family or volunteer time. Under the reference case approach, these costs are valued in monetary terms and added to other costs in the numerator (Gold et al, 1996). The Washington Panel further states that the usage of time in seeking treatment is not only a cost, but also an effect, especially when it has a positive effect on health states. Entering it in the numerator only takes it as a cost. In addition, if the time is trivially small or does not differ across regimens, its inclusion has little effect on the result and may therefore be omitted at the discretion of the analyst (Weinstein et al, 1997).

The Panel has received a lot of criticism especially from Brouwer et al (1997), Johannesson and Meltzer (1998) and Sculpher and O'Brien (2000). The bulk of the criticism centres on the problems of health state valuation such as the QALY. The valuation of health state is not intended to capture the impact of non-health related events such as loss of income. When health state valuation exercises do not refer to the effects of changes in income, then individuals may or may not implicitly incorporate these effects into their health state valuation (Brouwer et al, 1997). It is argued that the recommendation of the Washington Panel that productivity costs be included as part of the QALYs in the denominator will lead to inaccurate estimation of costs in CEA (Brouwer et al 1997). Since health state valuation usually relates to the entire period of illness, changes in income beyond the frictional period are already included (Pritchard and Sculpher, 2000).

2.4 FEATURES OF SUBSISTENCE ECONOMIES THAT REQUIRE A CLOSER LOOK AT INDIRECT COSTS

The general equilibrium and perfect labour market model in the case of the labour market may not be readily applicable in subsistence labour markets in developing countries. This is because it is a fact that labour markets in developing countries are not as efficient as those in developed ones. Rather, they are characterised by relatively high unemployment in urban settings and self-employment for survival in rural areas. Therefore, the wage rate and perfect competition to some extent are less relevant. The features of such a subsistence economy include the household as the unit of production rather than an individual. Moreover, being part of the social fabric is a major factor in one's ability to obtain assistance in times of need from family members and friends. Unlike many developed economies, issues of informal and unpaid work are central to measuring productivity loss.

Unpaid household work

The starting point in understanding household production is its definition. A household is defined as a person living alone or two or more persons living together as a single domestic unit who make common provision for food and other essentials of living, and occupy the whole or part of one dwelling unit (AusAID, 2003). A household need not strictly be one family; it could be a single person living alone or a group of two or more families staying together (Ironmonger, 1989). Unpaid work has been defined as "productive activities" for which no payment is received either in cash or in kind, including time spent in educational activities (AusAID, 2003). The New Household Economics literature (Reid, 1934) recognises the importance of the time and effort household members put into production activities for their survival. Reid's work gave prominence to household work through what she referred to as the "third party criterion". According to the third party criterion, any activity, household or otherwise, should be assessed on the basis that it can be performed by a third party for payment. Reid concluded that if it is theoretically possible to pay someone to perform a task, then there is a potential market for the goods and services. Therefore, typical household activities such as cooking, pounding grain and childcare fall into productive activities, while eating does not, as it may not be possible for someone to perform it for another person while the payer gets the satisfaction.

Hawrylyshyn (1977) reinforces the third party criterion by assuming that a third person could produce household activities without changing household utility, because they are all activities within the home, which have market substitutes. The value of the output is not attributable to the input of any particular person(s). Quah (1986) regards household work as the identification of production and consumption activities within the home. Gronau (1977) sees unpaid work like work in the market, which one would like to delegate to someone else to perform on his/her behalf because it is unpleasant.

According to Ironmonger (1996a), the economic statistics of work and production are used extensively in framing public policy and in business decisions. Therefore, it matters great deal what activities we perceive, define and measure as "work" and as "leisure". It is not only because this shapes everyday discourse, but because also the reporting on the measured "variables" actually affects our lives through practical government and business decisions (Ironmonger, 1996b, UNIFEM East and Southeast Asia Regional office Fact sheet 1 on Gender Issues, http://www.unifem-seasia.org/resources/factsheets/Gendis1.htm). Therefore, the main challenge in the measurement and valuation of unpaid household work is that it occurs outside of the market and there are no direct market prices associated with it. This is one of the main reasons Keynesian economists do not consider unpaid household work (Ogle, 2000).

In subsistence economies, a large proportion of women's time is spent on unpaid work (Leslie, 1989). Although the debate on the recognition of women's household work started as far back as 1898, the actual recognition by the United Nations came after the 1995 Beijing Platform for Action where the participants called for the inclusion of the work of women and all their contributions in the non-market household sectors as part of Gross Domestic Product (GDP) (Varjonen et al, 1999). Prior to that time, household work was excluded from the System of National Accounts (SNA) and was considered to have no economic value. However, following pressure from women's' groups, the United Nations (UN) Statistical Commission recommended the preparation of economic activities outside the market known as 'satellite' accounts (Ironmonger, 1996b): "Awareness of the economic importance of unpaid household work, and women's work in general, has led to the widespread acceptance that statistical measurements should be expanded to include unpaid work" (page 1). Although this may seem to be a new perspective, it was developed long ago as argued by Ironmonger (1996a), particularly by the pioneering work of Margaret Reid (1934) and Aslaksen et al (1996).

The system of under-reporting unpaid work does not only make developing countries seem poorer than they really are, but also makes their economic growth rate appear in a more favourable light than what it actually is (Ogle, 2000). Evidence has shown that rural women are active for an average of 18 hours per day and the average number of hours spent working, excluding eating, leisure and dressing times, ranges from six to 15, with median time in Africa being 10 hours and 10.8 in Asia (Leslie, 1989). Leslie went on to say that women in developing countries spend most of their time on agriculture, childcare and taking care of the ill.

Despite occupying a significant proportion of women's time, household work has not been given the attention it deserves. Some of the reasons for its exclusion are its independence from market activities, lack of data, which makes it difficult to estimate its real impact on communities and families in developing countries, difficulty of measurement and the inability to make historical comparison because unpaid services were not previously included in System of National Accounts (SNA) (Budlender and Brathaug, 2002). Kulshrestha and Singh argue that including household work in household final consumption means that all persons engaged in these activities would become self-employed, which by definition leads to zero unemployment (Budlender and Brathaug, 2002). Most of the previous time use studies conducted in the developed and developing world have concentrated on women and development issues, with no emphasis on the time use problems faced by women in balancing their time between their daily activities, reproduction and health roles (Mueller, 1984). The obvious gap in knowledge calls for the consideration of the inclusion of indirect costs, especially unpaid work, in economic evaluation. The various methods of the measurement and valuation of such costs is the subject of the next section.

2.5. REVIEW OF EMPIRICAL METHODS USED TO MEASURE AND VALUE INDIRECT COSTS

2.5.1 Introduction

This section explores the existing literature on the empirical measurement and valuation of unpaid household work.

2.5.2 Methods of time measurement

There are several methods of measuring time, each with its advantages and disadvantages. The most common instruments are direct questioning in surveys and time-diary methods (Kan, Man Yee 2006). The latter method has been referred to as the gold standard (Juster and Stafford, 1991; Juster, 1985).

This might be because of the long established belief by previous researchers that diary-based estimates of time use are more accurate than those from direct questions (Pelwis et al, 1990; Robinson, 1985). Some of the direct questions include activity log, stylised activity list, stylised time activity matrix, time activity matrix and time diary (Harvey and Taylor, 2000). Each of these methods can be combined with observation and/or recall methods.

Stylised estimates

Activity logs require the respondent to state the time taken to perform a particular activity for a given period by stating the start and end times for each activity. The method requires literacy and an understanding of conventional time. It also relies on the respondent remembering every activity. Stylised activity lists allow respondents to state how they spend the day doing each activity on the list. The method suffers from the danger of not having an exhaustive list and the inability to verify the authenticity of the responses given (Kinsley and O'Donnell, 1983; Robinson, 1984). A stylised time activity matrix is similar to the activity list but allows the inclusion of all possible activities and should add up to 24 hours (Harvey and Taylor, 2000). The method relies on the respondent to correctly assign activities to categories and on the good memory and calculation skills of the participants. A time activity matrix is a progression from the activity list by having both the list and time periods alongside each other which respondents record the activities and times. The time activity matrix has the disadvantage of relying on respondents to classify and categorise the activities provided (Budlender, 2004).

All the time use measurement instruments discussed above are collectively referred to as 'stylised estimates' for the simple reason that they ask respondents to state how they spend their time on certain activities (Juster and Stafford, 1985). Stylised estimates have the advantage of being cheaper than diaries because the information required from them can be easily obtained from surveys where time use is one of several variables (Kan, Man Yee, 2006). These survey approaches are also less demanding on respondents' time, initiative and energy than diaries, thereby leading to higher response rates. Some of the common disadvantages of stylised estimates include recall bias due to the difficulty for respondents to exactly state the time used. There is also a tendency to produce total time greater than 168 hours per week (Gershunny and Robinson, 1994) and there is less ability to verify the times recorded due to the fact that activity times do not add up to 24 hours (Kalfs, 1993).

Stylised estimates are based on responses to questions asking about the time devoted to various classes of activity in an average or normal or typical week (Juster and Stafford, 1985). Stylised estimates require respondents to recall their activities in the recent past and to carryout an appropriate form of averaging (Kan, Man Yee, 2007). Kan, Man Yee and colleagues went on to state that, based on the above requirements, the accuracy of stylised estimates depends on the difficulty of the task performed which might lead to substantial measurement error and the lack of detail which allows the respondent scope for choosing responses which correspond to the pre-existing and possibly inaccurate self-image (Kan, Man Yee, 2007).

2.5.2.1 Time use Diaries

Time use diary is the second type of data source that builds summary measures from activities in a time-diary and requires a respondent to keep a very detailed record of activities throughout each randomly selected day throughout the survey period (Kan, Man Yee, 2007). A time use diary is a research tool that requires participants to describe or record their daily events and experiences (van den Berg and Spauwen, 2006; Minichello et al 1999). In a time use diary, instead of providing the list of activities, respondents are expected to record for themselves the activities they perform in a day with their respective durations. Diaries can be in 'slot' or 'open' form. Slot diaries allow activities to be recorded alongside the given time span, say 15 minutes, 30 minutes etc, while open diaries ask respondents to write each activity with beginning and end times (Kan, Man Yee, 2006; Budlender, 2004; Bowling, 2002; Marino et al, 1999). Diaries could also be in the form of 'yesterday's' or 'tomorrow's' diaries. In yesterday's diaries, respondents are expected to record the previous day's activities, while in tomorrow's diaries, they fill the activities and their times as and when they happen. Yesterday's diaries can be filled through interviews, which make them suitable for those who cannot read or write (Harvey and Taylor, 2000). The three main types of diaries are traditional pen-and-pencil approach, which asks open or closed-ended questions on activity participation and time use; time unconstrained diaries, which allow for recording of activities including concurrent activities; and interview-administered diaries, which record at least primary activities but generally record primary and secondary activities (Harvey and Taylor, 2000).

Diaries, that are often preferred by researchers, have the advantage of chronologic reporting of activities (Scheuch, 1971), consistency in timing activity data by following activities through the day and forcing a full accounting of time. Diaries are less dependent on the respondents' involvement in terms of calculation of time on different activities, and hence produce more accurate measures (Kan, Man Yee, 2006).

Dairies also provide detailed information on the respondent's time use on various activities during the day, the sequence of these activities and the contexts of performing them i.e. with whom and where. Like stylised estimates, diaries are not error-free but are less likely to lead to systematic bias of records and distortions.

The main source of errors from diaries may be through recording or recall error and the day selected for diary-keeping may, by chance, be misrepresentative of a normal day activity. Furthermore, most time use surveys involving diaries have problems of limited coverage of their questionnaire because most people often view diary keeping as burdensome and cumbersome exercise for most respondents (Kan, Man Yee et al 2007).

When using time use diary, respondents could fail to fully remember the previous day's activities. This problem is overcome in the case of tomorrow's diary, which is the same as the time diary in all respects except that it is left behind for the respondent to complete as the day progresses and is later collected, and reviewed (Harvey and Taylor, 2000). However, the drawback is that it also requires an appreciable level of literacy to be able to record activities (Budlender, 2004; Scheuch, 1971).

Diaries also suffer from problems of capturing events beyond the primary activity. Missing or unclear data may be difficult to complete or clarify, and if the researcher contacts participants to obtain the missing data, then the data becomes retrospective and subject to recall errors and biases (Roghmann and Haggerly; 1972; Verbugge, 1980). A key problem often associated with unconstrained diaries is that there is a tendency to end up with a day of more than 24 hours if one tries to add up all the time spent in any one activity. This may be difficult to reconcile at the analysis stage. Completing diaries for several respondents could be a difficult task leading to low response rates and less thorough reporting (Kan, Man Yee, 2006). This is especially so during prolonged periods of diary use (Verbugge, 1980; Marino et al, 1999). Diaries are relatively costly both in terms of the volume of data to be collected and require a lot of time from respondents and researchers (van den Berg and Spauwen, 2006). For the researcher, it could be in the form of time required to train diary keepers and maintain their support (Verbugge, 1980). Finally, diaries cannot be used in certain instances where they are likely to incriminate respondents. These include reporting illicit drug-use or recording income that has not been declared to tax authorities (Marino, 1999).

A recent study using pictorial diaries to collect household health consumption and expenditure in Tanzania and The Gambia (Wiseman et al, 2005) observed that pictorial diaries could be used successfully in predominantly illiterate communities to collect data on a range of patient health questions. Wiseman et al (2005) identified respondent fatigue as a problem of using diaries. The authors however acknowledge that this phenomenon does not always lead to poor quality data. The study recommends a number of different techniques that field teams can use to support diary keepers in order for them to minimise problems of fatigue. These include regular interviews with diary keepers as well as the use of aid-memories and other prompts. In terms of costs, those conducting studies involving diaries were advised to set aside enough funds to support these techniques and provide adequate training for fieldworkers. Finally, Wiseman et al (2005) attributed the success of diaries to a trusting relationship between fieldworkers and the diary keeper.

2.5.2.2 Observation

The observation method of time use data collection requires direct observation and recording of events by an outside observer. It requires the subject of the study be followed as he or she performs work for some days (Budlender, 2004). It involves directly observing the person doing unpaid work and recording the time it takes to perform each activity without the direct involvement of the one being observed, and gathering data in a systematic way (Kalfs, 1993). The two main types of observation methods are direct and random observations. The former entails direct observation and recording of activities/events by an outside observer as they take place. The latter creates a sample of time to be observed through what is known as fixed interval sampling or random interval sampling (including random spot checks) (Harvey and Taylor, 2000).

The main advantage of the observation method is that it allows data to be gathered in a systematic way and is useful where activities are not structured and several activities are performed simultaneously by several people (Khan et al, 1994). Furthermore, the method does not require the one being observed to be educated or to have an understanding of conventional time.

The main disadvantage of the observation method is that it is resource-intensive in terms of time and staff as it requires observing one person at a time. Observing more than one person at a time would require visiting those being observed at regular intervals, which could compromise reliability (Kalfs, 1993). The fact that the respondents know that they are being observed could lead to changes in behaviour in the form of 'play-acting'.

Furthermore, direct observation could be highly intrusive and disruptive to work and may possibly compromise the actual behaviour (Harvey and Taylor, 2000). Harvey and Taylor further argue that, due to its intrusive nature, periods of observation are usually limited to daytime, which could be a problem in measuring the work of women in developing countries, which extends into the night. A few other additional drawbacks from observing people directly include the fact that one does not know the focus of someone's attention if they are doing simultaneous activities and therefore may not pick up an important element of the detail of the activity (Kimberly Fisher, personal communication, London, 2005). For instance, food may be prepared for one's own household or a special meal for someone in the extended family or a neighbour who is ill and needs extra assistance. Generally, some time use surveys tend to separately code activity undertaken for one's own household and extra activity undertaken as unpaid help to someone from another household, but this may not necessarily be picked up from observation. It is almost impossible to observe everything using the observation method because the observer still has to undertake essential activities, among them, eating, going to the toilet and, resting, during the day.

2.5.2.3 Recall

The recall method asks participants to retrospectively recount events, tasks, reflect on the various work situations and then report on their reactions, feelings or actions (van den Berg and Spauwen, 2006; Csikszenmihalyi and Larson 1987). The method is advantageous in that it is less intrusive and is usually cheaper to administer in terms of both financial and human resource costs than observation methods (Harvey and Taylor, 2000). The recall method can be conducted via a questionnaire or via a diary or interview. The method is less demanding on both respondents and researchers (van den Berg and Spauwen, 2006).

The main disadvantage of the recall method is that the data it generates can suffer from under-reporting of events, memory distortions, selective memory or reinterpretation of past experiences due to recall bias (van den Berg and Spauwen, 2006; Csikszenmihalyi and Larson 1987; Tidwell, Reis and Shave, 1996). The recall method, compared to observation, is a less systematic way of questioning time use information (van den Berg and Spauwen, 2006). One other problem is that there may be no way to determine the circumstances that led to specific events, contextual to the event recorded, or the exact time when such events took place (Minichello et al 1999).

Verbugge (1980) argues that infrequent, major or events of high emotional importance are generally well reported because people usually tend to remember them, but the tendency to have lapses in memory or telescoping (i.e. remembering events but not their correct date) can be a problem under the recall method. There is also the issue of the recall period, or how recently the activities took place.

The farther back one asks people to remember, the more inaccurate their memory is likely to be unless the activity is particularly memorable. Nonetheless, if one's activity of interest is an infrequent one, such as preparations for a wedding, recall may be the only option (Kimberly Fisher, personal communication, London, 2005).

The decision to use recall or other methods depends on the level of detail of activity history one seeks. If one's interest is in a particular type of activity, such as the role a person has played during the harvest, some reasonably valid information can be obtained about a particular activity (as opposed to all activities) by using interview techniques to help people reconstruct their past and using prompts to help them remember certain forms of activities (Kimberly Fisher, personal communication, London, 2005).

From the review, it is clear that each method of time-measurement has its advantages and disadvantages. For instance, the stylised estimates are generally cheaper to administer than diaries and observation methods. Observation combined with diaries requires a lot of resources to administer which may not be the case in stylised estimates. In all types of self-reporting, one relies on respondents to decide which activities to report and this is compounded in some cases, by categorisation problems. Furthermore, regardless of the methods used, there is the perennial problem of simultaneous activities (i.e. when more than one activity takes place at a given point in time). Taking simultaneous activities on board (if not done carefully) could lead to more than 24 hours in a 24-hour day and ignoring them could lead to understating time use (Budlender, 2004). The likely implications of all these is that, the choice of a method depends to a large extent on many factors, not the least of which being the resources available and the ability of the researchers to support and guide participants to accurately record their activities.

2.5.3. Methods of valuing time

Household work has been referred to as a residual value derived indirectly by deducting from the final market value of household production the cost of materials and imputed capital inputs (Ironmonger, 1996a). However, since our focus is at the microeconomic level, one would have to look for alternative methods.

The work of Goldschmidt-Clermont (1987) divides *time* valuation methods into input and output. As indicated in Section 2.3.2, in each case – input and output method – the human capital method is used to value unpaid labour (Klarman et al 1968; Weisbrod, 1964).

Output-related evaluation of household production is the output of household production expressed either in physical units (volume) or in monetary units (value). Goldschmidt-Clermont (1987) further divides the approaches into market cost, replacement cost, opportunity cost, reservation wage and the spouse paid wage approach. Any of these methods are used with HCA. As stated in Sections 2.3.3, FCA does not recognise unpaid work and WPA does not consider indirect costs let alone unpaid work as part of the denominator. However, a slight shift in this position of the Erasmus School that has been observed of late was discussed in Section 2.3.3.

2.5.3.1. Input-related method - HCA

Input-related method is divided into two. One takes into account the value of inputs and the other takes the volume of inputs into consideration.

Value of inputs

The input-based approach involves direct imputation of labour input and the valuation of the production costs of inputs. The amount of labour time used in household work is assessed and then multiplied by a wage rate to determine the 'income' from the household production, which is referred to as the value of unpaid work (Young, 2000). The possible wage rates are:

1. The average wage for all workers in the economy;
2. The average wage for all female or male workers;
3. The minimum wage;
4. Wages paid to subsistence domestic workers;
5. Wages for specialist workers for each task undertaken; and
6. The wage applying in a market enterprise for performing equivalent work.

Methods 1 to 3 are known as the 'opportunity cost approach', where the value of household work is derived from the potential earning in the market if the person was not engaged in household work. Methods 4 to 6 are known as the 'replacement cost approach', where the value of household work is obtained from what it would take to pay someone to perform the work at the household level.

The opportunity cost approach is based on the economic concept of the opportunity cost (Section 2.3.2) of forgoing the benefit of household work for an alternative based on the estimated earnings from paid rather than unpaid work (Budlender, 2004).

The method uses the potential wage rate in the labour market based on education, experience, age, sex and location (Young, 2000). Therefore, the value of household work depends more on the person doing the work than the work itself. The opportunity cost approach opens the way for one to use any of the wage rates as stated in methods 1-3. This could be the mean wage per hour in the economy calculated separately for males and females or the average of the two, assigned according to the person performing the unpaid work or minimum wage rate. When the minimum wage rate is used, labour input into household work is assigned an imputed wage equal to the minimum market wage rate.

The replacement cost approach is the wage paid to a polyvalent substitute such as a domestic servant performing all household work (generalist) or a wage paid to a specialist like a cook who performs only one specific task (Goldschmidt-Clermont, 1987). The generalist approach uses the mean wage of the worker performing similar work to the unpaid person such as wage rates for maids or childminders (Budlender, 2004). The specialist approach focuses on the activity itself rather than the person performing the work. For each activity, it uses the wage earned in the market by a worker whose function and circumstances match the unpaid work. For instance, cooking time is valued at the hourly pay for a cook, and cleaning work at the wage rate paid to a cleaner (Budlender, 2004).

Disadvantages of using wages in valuing time

Wage-based methodologies have general and specific problems worth highlighting. Using market wage as a proxy to estimate opportunity cost of unpaid household work is likely to overstate the time value of unpaid work (Ironmonger and Sonius, 1989). Budlender and Brathaug (2002) also argue that one of the main disadvantages of the opportunity cost method is the variation in wage rates when different people perform the same type of unpaid work, because the pay rate of a specialist may be different from that for an ordinary housewife. They went on to argue that, in a situation of high unemployment, it is difficult to find the opportunity cost for the unemployed and economically inactive, and hence it is difficult to assign suitable paid work to unpaid work, let alone find an appropriate wage rate.

Moreover, it is assumed that certain household tasks, such as cooking, command a specific wage. However, compared to those in the household, workers in the market are in a better bargaining position to negotiate their wages (Skolka, 1976). Therefore the use of this value for the economic evaluation of unpaid work raises problems even in the context of developed countries, and more so in countries with different social values and economic structures (Oppong, 1982).

The theory of substituting market and non-market work is based on the marginal value of the market time, which is assumed to substitute the last unit of the non-market time and market work until equilibrium is reached (Goldschmidt-Clermont, 1982, 1987). This substitution of work in the two sectors is questionable in settings where household work limits the freedom to choose how best to allocate the marginal time units.

The generalist approach has been criticised because it may undervalue unpaid household work by ignoring management responsibilities attached to household work. The specialist wage rate approach ignores the difference in productivity and efficiency between market and non-market production and assigns different wages to activities regardless of who performs them. The approach attempts to match as closely as possible the work of paid and unpaid work, but has the tendency to overvalue unpaid labour (Budlender and Brathaug, 2002; Young, 2000).

Further problems with wage-based methodologies include the tendency of females to perform more unpaid work than males and hence having a lower average wage. The wage-based methodologies, which are generally based on only the wages of the employed population, may not necessarily represent the average wage when unpaid work is factored in. Unpaid work could be done as part of leisure and as such, it can take a much longer time than usual and in the process exaggerates the value of time (Australian Bureau of Statistics, 1990). One other common problem of wage-based evaluations is how to deal with simultaneous activities in cases where time is spent doing two or three activities at the same time. Quah (1986) suggests only considering the time of "major" or "primary" activities. This issue is resolved in the output method below.

Volume of inputs

According to Goldschmidt-Clermont (1987), this type of input-based approach requires physical counting of the number of persons or hours and then compares the volume of work input in household work with the volume of work input in market work. Alternatively, the volume of household product for example laundry can be compared to the output of commercial laundry. However, there is the perennial problem of adding or subtracting the physical quantities, which can be difficult. This is often solved by converting physical units to monetary units. The conversion is done by borrowing values from the market, which consists of wages paid for work similar to household work. In that case, the method will also suffer from the disadvantages of wage-based methodologies highlighted earlier.

2.5.3.2. Output-related method-HCA

This approach requires the identification and quantification of household outputs such as cooked meals and their market value in terms of prices at which the household will sell or the prices at which the household can buy an equivalent market product (Young, 2000). It corrects for differences in productivity levels by focusing less on the means of production and more on what is produced (Budlender, 2004).

The steps in estimating the volume of household output in the various domestic activities include valuing the output at the market price (producer/retail price), and then deducting intermediate consumption (consumption expenditures for intermediate goods or market value of non-market production goods in the production process). For goods or services with no market equivalent, an input-related evaluation is used as a complementary method by estimating the volume of labour inputs (in labour units) and assigning their market values (Ironmonger, 1989). Depending on data availability, it can be the net returns to labour (exclusive of intermediate consumption) in market-oriented activities performed by the household.

One of the main difficulties with the output-related method is how to match household work with market work and use the appropriate prices, especially in developing countries (Goldschmidt-Clermont, 2002). There are also difficulties in whether to use producer or retailer prices. For the valuation of subsistence agricultural products, Blades (1975) and Fish (1975) stress the importance of indicating the purpose of the evaluation as a pointer to the type of category of prices. Retail price is used when produce cannot be sold at the farm gate. In this instance, the producer price is recommended. In the case of households, the choice of price depends on the purpose of the evaluation.

2.6. REVIEW OF THE EMPIRICAL LITERATURE ON ECONOMIC EVALUATION OF PREVENTIVE HEALTH CARE

2.6.1. Introduction

This section is devoted to the review of the empirical literature on economic evaluation of health interventions. The review focuses on how cost-effectiveness analyses of preventive health interventions identify, measure and value indirect costs. The detailed criteria for the assessment are as per the attached information extraction tool (Appendix 1). The review findings are presented under sub-headings: method; results; and discussion. The section ends with a summary of the findings and key gaps to be filled by this research.

2.6.2 Methods

The review combined several search strategies to identify relevant studies. The main strategy was to conduct an electronic search using two computerised databases: MEDLINE and Health Economic Evaluation Database (HEED), for economic evaluation studies that include indirect costs. Since not all articles were indexed in the databases, in order to obtain those likely to be omitted or poorly indexed, "grey" literature of unpublished work, including those found in references of other PhD theses, books, pamphlets known to the candidate with materials relating to economic evaluation and indirect costs, were hand-searched to determine their relevance to the study. Other relevant sets of studies that the candidate knew were cost-effectiveness studies involving indirect costs but were not captured electronically were added for review. The reference list of economic evaluation articles found were scrutinised for additional empirical studies that could have been omitted using other strategies. The search terms used in all databases included the following: *economics, costs, cost analysis, burden of illness, cost-effectiveness analysis, indirect cost, productivity costs, unpaid work, domestic work, household production, household work, informal work, subsistence work and wage labour.*

The period for the systematic review was 1996-2006, as the results of earlier studies were considered too old to be relevant to the current economic evaluation focussing on indirect costs. Studies were included from the literature search, if they were in the English language. Also included were full economic evaluations (CEA) that examined at least two alternative interventions incorporating indirect costs rather than just referring to them. This is because CEA and CUA are the two methods of economic evaluation methods that can use any of the three methods of indirect costs valuation (HCA, FCA and WPA).

While the use of indirect costs in CEA and CUA is of interest to the researcher, for pragmatic reasons and given the fact that CEA is the dominant economic evaluation method in developing countries, it was decided to focus the review on empirical CEA that used indirect costs regardless of the outcome used. Those applied cost-effectiveness studies considered were on prevention, screening, diagnosis etc. Studies were also left out from the review if they were economic evaluation of treatment or therapy. Treatment or therapy studies were excluded because the decision to seek treatment may involve other considerations such as pain, suffering, discomfort, which may compel people to ignore cost considerations in seeking care (Ratcliffe, 1993). Empirical studies applied the concept of indirect costs in preventive health care whilst the methodological studies looked at the method of measuring them. The review articles, as the name implies, review other works in the same areas.

Since some of the articles were repeated across the two main databases, further sorting was done by recording the name(s), date of publication and page numbers of the selected articles from HEED to eliminate repetition. Titles and abstracts were read to assess their relevance to this review. The studies that met the inclusion criteria were reviewed.

Descriptive categories were used to summarise each article in terms of the method used to estimate indirect costs. The details of the analytical categories are presented in Appendix 2. After reviewing the methods used in each study, the importance of indirect costs on overall cost-effectiveness ratio (ICER) was assessed. The specific issues that were assessed included:

1. The study setting and population,
2. Type of intervention
3. Methods of identifying and measuring all relevant costs;
4. Methods used to measuring indirect costs;
5. Approaches of valuation of indirect costs
6. Consistent use of indirect costs;
7. Costs disaggregated; and
8. The effects of indirect costs on the overall result assessed through sensitivity analysis.

2.6.3 Results

After both the electronic and hand search, 210 articles were initially identified for review. However, a thorough reading of the abstracts showed tthat only 81 papers fulfilled the inclusion criteria. The geographical distribution of the 81 cost-effectiveness studies showed that 46% of them came from North America (USA and Canada). The single country with the largest number of studies was USA with 41% of all the papers reviewed. The proportion of articles reviewed from the USA is more than those from the whole of Europe (37%). The least represented geographical area is South America with only 1%. The rest of the continents, Africa, Oceanic fell between the range.

In terms of study population, the picture is mixed, with 32% focusing on adults and 26% on women. Amongst the proportion for all women, 7% considered only pregnant women. About 16% considered all age groups while 15% considered only children. The rest represent infants (9%) and men (2%) as indicated in the summary Table 2.1. In terms of the type of intervention, out of the 81 studies, 35% were on screening for various conditions such as Chlamydia, 20% on mainly childhood vaccination programmes and 40% on prevention of diseases such as HIV/Aid and Tuberculosis (TB).

The rest is a mixture of interventions. Only three studies are on malaria (Gonzalez et al, 2000; Aikins et al, 1998; Wiseman et al, 2003) and none on malaria in pregnancy, which is the focus of this research.

In terms of separating costs, half of the studies clearly presented costs in terms of direct and indirect components. Among them were Marissal et al 2000; Welte et al 2000a; 2000b; and Johannesson et al, 1996. The valuation of paid and unpaid work, like their identification, differs in many ways across studies. Thirty-eight percent of all the studies used paid work to value indirect costs. The use of unpaid work to estimate indirect costs instead of paid work in most cases has not been common. Only 2% considered unpaid work alone as part of indirect costs (Krahn et al, 1998; Fox-Rushby et al, 1996), one study considered household work time as the main determinant of indirect costs (Grover et al, 2003). Various other methods were used to value unpaid work. These include the average wage rate (Gow, 1999); gross salary plus taxes (Dayan et al, 2001); proportion of gross salary (Aikins et al, 1998) and previously lost income (Aledort et al, 2005). Gonzalez et al (2000) combined both paid and unpaid work using Tanzanian minimum wage to estimate unpaid work and Welte et al (2000b) considered unpaid work time only in the sensitivity analysis. Others valued unpaid work time using an average wage, agricultural and household work times. The rest of the studies were not explicit on the value of unpaid household work.

Eleven percent of the studies did not classify their forgone time in terms of paid, unpaid or leisure. Instead, they identified them in terms of social cost, lost productivity and average wage without indicating whether they are paid or unpaid. The opportunity cost of leisure was considered by only 1% of the studies (Brisson M and Edmunds, 2002). Most studies used paid wages as a proxy for unpaid work. The shortcomings of this approach have already been highlighted in Section 2.5 on methods of measuring unpaid work.

Among the three approaches used to value indirect costs, the most common method was HCA with 63% of the studies using this technique. FCA was used in 3% of the studies (Valkengoed et al, 2001; Warner et al, 1996; Smith et al, 1997;) and WPA in 5% (Karim et al, 2004; Stinnett et al, 1996; Bell et al, 1999; Beutels et al, 1996). Only one study combined HCA and WPA (Welte et al 2000b). It could not be determined from 27% of the studies as to the methods they have used. From the 81 studies reviewed, 74% have disaggregated their costs into the various components and the rest did not. Only 42% of the studies conducted sensitivity analysis to test the significance of indirect costs on their results. Out of that proportion, 31% found indirect costs to be significant to their findings.

Table 2.1 Summary of cost-effectiveness studies reviewed

Variable	No. of studies	%
Geographical setting of the studies		
Africa	8	10
America (North)	37	46
…from which USA alone	33	41
Europe	30	37
Asia	2	2
Oceanic	3	4
South America	1	1
Study population		
Infants	7	9
Children	12	15
Pregnant women	6	7
Women	15	19
Men	2	2
Adults	26	32
All age groups	13	16
Type of intervention		
Vaccination	16	20
Screening	28	35
Prevention	32	40
Others	5	6
Foregone time		
Paid work	31	38
Unpaid work	2	2
Paid & unpaid work	13	16
Leisure time	1	1
Others	25	31
Not stated	9	11
Approach used to measure indirect costs		
HCA	35	43
HCA (inferred)	16	20
FCA	1	1
FCA (Inferred)	2	2
WPA	4	5
HCA & WPA	1	1
Could not be determined	22	27
Indirect cost disaggregated from other costs		
Yes	60	74
No	21	26
Effects of indirect costs on results assessed through sensitivity analysis		
Yes	34	42
No	47	58
… of those who assessed the effects of indirect costs,		
Significant	25	74

2.6.4. Discussion and gaps in the literature

The results of the review should be viewed in the context that not all the abstracts were very clear as to whether they have included indirect costs or not. Therefore, the potential to exclude some studies that actually included indirect costs exists. In the same way, including studies especially those not very clear about their methodologies is also a possibility. However, this is not expected to change the general direction of the findings.

There are no doubts that many studies have incorporated indirect costs in the CEA of preventive health services. This is demonstrated by the number of papers reviewed (81) over a 10-year period (1996-2006). The general finding of the review is that, the use of indirect costs varies between settings. Moreover, since many of the studies were conducted in developed world dominated by paid work, this puts into question the transferability of their findings to the developing country set-up. This is mainly because the level of development, the social set-ups, access and utilisation of health services are mostly different in the two settings. In addition to the general findings, the specific areas assessed include:

(i) Disaggregating costs into direct and indirect costs
(ii) Selection of forgone activities such as paid, unpaid or leisure
(iii) Approach used to value indirect costs i.e. HCA, FCA, WPA or their combination
(iv) Use of sensitivity analysis to assess the impact of indirect costs on the results

After the publication of several guidelines on economic evaluation (Section 1.1), one would expect that by now, studies would have moved towards convergence in standards. However, the fact remains that a lot of disparity exist in the way studies incorporate, measure, value and even emphasise the role of indirect costs in CEA. The review revealed inconsistencies in terms of the way costs are apportioned, especially with respect to direct and indirect costs. Most of the studies indicated that they have disaggregated their costs but the method of disaggregating is not consistent across studies. This is in contrast to the suggestion that costs should be disaggregated into the various components of direct, indirect and even intangible costs so that anyone looking at the studies could use a component or a combination for their purposes. In the review, 26% of the studies did not disaggregate their costs into various components. It is therefore very unlikely for anybody to assess the effects of indirect costs on the results of that 26%. In valuing indirect costs, both the quantities and cost per unit are very important because it helps give a breakdown of the various parts of the aggregate term that could be used by others. However, it will be difficult to multiply the resource use and their respective unit costs. Another reason for disaggregating costs was to assess the effect of each of the components on the overall result or variables of interest.

In terms of identification of the foregone activities, the review findings showed that most of the studies focussed on paid work at the expense of unpaid work and leisure times. The various points of view concerning the inclusion of indirect costs including paid, unpaid and leisure times in economic evaluation have been adequately reviewed in Section 2.3. As indicated earlier in Section 2.6.3, the fact that only 2% of the studies actually considered unpaid work leaves a gap for subsistence economies. Like in developed countries, in order to improve efficiency at health facilities, developing countries may move towards reducing the length of hospital stay in favour of informal care at home. This may lead to higher demand for the time used for subsistence work and hence a bigger role for unpaid work in economic evaluation. Section 2.4 devoted a lot of time on the unique features of subsistence economies that warrants a shift away from using only paid work in favour of unpaid work. However, the number of studies that used unpaid and household works is less than the number of studies conducted in subsistence settings. This shows that not all the studies reviewed from subsistence economies use unpaid or household work.

The details of how different schools of thought value indirect costs are highlighted in Section 2.3. Going by the various arguments, one would expect that all the 81 studies reviewed would have used at least one of the approaches. However, despite the arguments as to which method is suitable for valuing indirect costs, few directly and clearly stated the approach used to value indirect costs (i.e. HCA, FCA or WPA). Among those that indicated the approach taken, the majority used HCA, two used FCA and WPA and the rest either implied the approach they used or failed to indicate their approaches they used. The candidate had to infer the approach used in 22% of the studies because the authors did not explicitly indicate them but could not infer 27%. The existence of the possibility to infer the approach used in some of the studies leaves a lot of room for subjective interpretations.

The final point relates to the first, largely because, it is only when indirect costs are disaggregated from the rest can their effects be assessed on the overall results through sensitivity analysis. All the studies reviewed took societal perspective, which means they expect a role for indirect costs. The opportunity cost of different forgone activities such as subsistence farm work, unpaid household work, paid work and travel when disaggregated from the outset to enable one to assess the impact of each on the intervention. However, 58% of the studies did not conduct sensitivity analysis to assess the effects of indirect costs on their results. Some of the few exceptions are Welte et al (2000a; 200b), Aikins et al, (1998), Lindholm et al, (1996), Mansergh et al, (1996). Aikins et al (1998) conducted multiple sensitivity analyses on several parameters including transport costs.

Mansergh et al (1996) included loss of productivity of HIV-infected infants in the sensitivity analysis. The fact that 31% of the studies that assessed the effects of indirect costs on their results through sensitivity analysis found them useful shows that such costs have roles in CEA.

In summary, the inclusion of indirect costs in CEA is still work in progress because very few studies incorporate all the main concerns of disaggregating costs, clearly stating the forgone activities and approaches used and conduct sensitivity analysis. One of the main omissions of the studies included in this review is the clear separation of costs into direct and indirect costs. Some of the studies tend to aggregate the cost components and in the process mask their individual contribution to the overall result. The distinction between paid and unpaid work, especially household work, is rarely made clear. Despite being one of the major activities in subsistence economies, the role of unpaid work, especially household work, has not been given the attention it deserves. Most of the studies took into consideration the formal labour market (paid work) and only in very few instances were subsistence labour markets considered. All the above are likely to have effect on the overall results of the study and unless these inconsistencies are tackled, there is likely to be many disparities in studies.

2.7 SUMMARY

This chapter reviews literature on economic evaluation methods, approaches to valuing indirect costs, unpaid work and empirical literature on the use of indirect costs in cost-effectiveness analysis. The first section gave an overview of the basic forms of economic evaluation. It was revealed that CEA, CUA and CBA are the three main types of economic evaluation each with its advantages and disadvantages. The conventional approaches to valuing indirect costs, HCA, FCA and WPA were critically reviewed with respect to their use in economic evaluation. The unique features of developing countries showed that the conventional measurement and valuation methods of indirect costs cannot be readily applied in such settings. In recognising that fact, possible ways of measuring and valuing time were reviewed through time use methods. The chapter ended with a review of the empirical literature on indirect costs, which revealed an important gap in terms of the inclusion of indirect costs in cost-effectiveness analysis. This exists despite 31% found indirect costs to be significant in their overall cost-effectiveness ratios.

CHAPTER 3: MALARIA IN PREGNANCY

3.1 INTRODUCTION

This chapter reviews the literature on malaria in pregnancy in developing countries. It first reviews the general literature on malaria in pregnancy in Section 3.2 before focusing on low birth weight (LBW) and anaemia in Sub-Saharan Africa (SSA) in Sections 3.3 and 3.4 respectively. Emphasis is placed on morbidity, mortality and the categorisation of LBW and anaemia into the various types. Section 3.5 focuses on interventions in low-income countries in general, with emphasis on the prevention and control of malaria including malaria in pregnancy. Review of economic evaluations of malaria in pregnancy in SSA is covered in Section 3.6. The chapter ends with a brief summary (Section 3.7).

3.2 METHODS

Major databases such Medline, PubMed, Popline and trial register and bibliographic databases of malaria in pregnancy library were searched for relevant articles using a combination of the following keywords: *malaria, pregnancy, antenatal care, intermittent, preventive, treatment, prophylaxis, sulphadoxine-pyrimethamine, chloroquine*. The focus was on articles published from 1980 to June 2007. However, one article published in 1964 was exceptionally included because of its relevance to the subject under review. The articles from the databases were supplemented with relevant information on malaria in pregnancy from conference articles, information from websites of Roll Back malaria (RBM), WHO, UNICEF, Centre for Disease Control (CDC), Multilateral Initiative on Malaria (MIM) etc. Full text articles were obtained from London School of Hygiene and Tropical Medicine Library and electronic databases, WHO Global Information Full-Text (GIFT) site and Google where available. GIFT is a WHO initiative that provides free online full-text journals. The reference lists of full text articles were searched for additional references. Some of the known experts in malaria in pregnancy known to the candidate were contacted for relevant information. WHO Headquarters were contacted for detailed literature on malaria in pregnancy and they provided a comprehensive list of references.

Most of the articles selected for review were written on developing countries with emphasis on Sub-Saharan Africa (SSA). Excluded were articles: Written in languages other than English, on other strains of malaria other than *Plasmodium falciparum* and from malaria endemic areas outside SSA. The articles on distribution of LBW and anaemia were searched from the same sources listed earlier. However, the main criteria for inclusion were articles that showed distribution of LBW and anaemia with focus on SSA regardless of cause.

Papers showing distributions of the two conditions in other areas were excluded. In order for the review to be as close as possible to the situation in The Gambia, the bulk of the studies selected was from the West African sub-region. Articles on the cost-effectiveness of malaria interventions were obtained from the same sources and from references of published reviews such as Goodman et al (2001) and Worrall et al (2007).

3.3 RESULTS

Malaria in pregnancy is a serious health risk to pregnant women but is a preventable cause of maternal and perinatal morbidity and mortality (Brabin, 1983; Brabin, 1991; Menendez, 1995). It is frequent, severe and more common in pregnant women and the early postpartum period than in the same women before pregnancy and in non-pregnant women (McGregor, 1984; Diagne et al, 2000). The effect of *Plasmodium falciparum* ranges from increased attractiveness to mosquitoes to continuing morbidity postpartum (Lindsay et al, 2000, Diagne et al, 2000). Lindsay (2000) indicates that pregnant women are twice as attractive to malaria mosquitoes as non-pregnant women.

In areas of high and moderate (stable) malaria transmission, malaria is frequently transmitted from person to person leaving women with a high level of acquired immunity to *Plasmodium falciparum* malaria (Desai et al, 2007). The women are often asymptomatic due to low peripheral parasitaemia but there is a high prevalence of placental infection (WHO, 2002). In most parts of Africa where *Plasmodium falciparum* malaria is endemic, exposure to malaria parasites is intense and the adult population is relatively immune. Pregnant women however, — particularly primigravidae, are immuno-compromised (Menendez, 1995). The immune system is said to be immuno-compromised when the defence mechanism for malaria infection has been lost through disease or treatment (Dr. M. Jawla, personal communication, Banjul 2006). In such areas, pregnancy leads to a reduced effective immune response and in particular, the placenta provides a protected site for parasite sequestration and growth. Malaria parasites are often found sequestrated in large numbers in the placenta, without any being found in the blood (Beeson et al, 2002). According to Rogerson et al (2003), a study on the sensitivity for diagnosing malaria found 47% for parasites in the peripheral blood, 63% for slides dabbed onto the placenta, and 91% for placental histology.

This reinforces the view that a negative blood slide for malaria parasites does not necessarily mean there is no malaria for semi-immune pregnant women. However, for non-pregnant adults, a negative slide means no malaria.

Parasite sequestration occurs along the surface of the placental membrane whereby parasites impede oxygen-nutrient transfer and the consequences contribute to the complications experienced by both the pregnant woman and the unborn foetus (Dr. M. Jawla, personal communication, Banjul 2006). Research into *Plasmodium falciparum* in the past decade or so has shown that parasites bind to specific ligands in the placenta, especially chondroitin sulphate A (CSA) though this is not the only one (Beeson and Brown, 2004; Mahusamy et al, 2004). Anti-CSA antibodies inhibit binding adhesion to the placenta over time, which is believed to be the reason for the reduced risk of malaria in pregnancy as the number of pregnancies increases (Fried et al, 1998).

The main effects of malaria in pregnancy in stable areas are associated with malaria-related anaemia in the mother and with the presence of parasites in the placenta (Steketee et al, 2001; Shulman et al, 1999; Mutabingwa et al, 1993). The resultant impairment of foetal nutrition contributes to LBW, which is a leading cause of poor infant survival and development in Africa (MacCormick, 1985; Steketee et al 1996b; Bloland et al, 1996). Placental malaria is often not accompanied by a patent peripheral parasitaemia, so infection cannot be reliably screened through antenatal clinics (Shulman et al, 2001a; Mockenhaupt et al, 2002; Rogerson et al, 2003). The resultant effect is that the majority of such women do not seek care for malaria (Steketee et al, 1996e).

In areas of epidemic or low (unstable) malaria transmission, malaria is infrequently transmitted from person to person leaving adult women with a low level of acquired immunity, which exposes them to illness when infected with *Plasmodium falciparum* malaria (RBM, 1998). Due to little or no immunity to malaria, pregnant women are likely to suffer from complicated malaria in the form of cerebral malaria, hypoglycaemia, hyperpyrexia, severe haemolytic anaemia and pulmonary oedema and acute renal failure (WHO, 2000a). According to Luxemburger et al (1997), pregnant women in such areas are two to three times at greater risk of developing malaria and severe disease than non-pregnant women. The resultant effects of malaria are death from severe malaria or through indirect causes such as malaria related anaemia (Luxemburger et al, 1997; Hammerich et al, 2002). Furthermore, *Plasmodium falciparum* may increase the risk of miscarriages, pre-term births, maternal anaemia, spontaneous abortion, stillbirth, LBW and neonatal death (Foresu et al, 2004; Steketee et al, 1996b). *Plasmodium falciparum* is said to be responsible for the death of approximately 200,000 infants each year (Steketee et al, 2001) as well as maternal illness and death, central nervous system complications and adverse reproductive outcomes (Steketee et al, 1996d; Luxemburger et al, 1997; Meek, 1988).

The effect of malaria in pregnancy is parity-specific (WHO, 2002) with the risk falling with increased gravity (McGregor, 1984). Primigravidae and secundagravidae are generally more affected than women in subsequent pregnancies (Ricke et al, 2000; Staalsoe et al, 2004). During the first malaria-exposed pregnancy, immunity to malaria develops in the placenta, which has no effects in the first pregnancy but is retained in the uterus and increases cumulatively in subsequent pregnancies (WHO, 2002).

This could be the reason women in the first and second pregnancies are more affected by malaria than women in subsequent pregnancies. Studies in eight countries in SSA showed that primigravidae had higher prevalence of peripheral and placental malaria infection compared to multigravidae (Keuter et al, 1990; Mvondo et al, 1992; Bulmer et al, 1993; Meurias et al, 1993; Mutabingwa et al, 1993, WHO, 2004). The difference between those infected in terms of mean haemoglobin levels (McGregor, 1984; Brabin et al, 1990a) and mean birth weight (McGregor et al, 1983) was more marked in primigravidae than multigravidae. However, a study in Senegal showed that the incidence of malaria attacks in pregnancy significantly increased for multigravidae up to their fifth pregnancy (Diagne et al, 1997).

Human Immunodeficiency Virus (HIV) infection diminishes a pregnant woman's ability to control *Plasmodium falciparum* infection (Steketee et al, 1996b) and therefore, the prevalence and intensity of malaria in pregnancy is higher in HIV positive women (Steketee et al, 1996b; van Eijk et al, 2002; van Eijk et al, 2003; Verhoeff et al, 1999). HIV positive women are likely to have symptomatic infections and increased risk of malaria-related adverse birth outcomes (van Eijk et al, 2003; Ayisi et al, 2003). Multigravidae with HIV infection are similar to primigravidae without HIV infection in terms of susceptibility to and negative consequences of malaria infection (van Eijk et al, 2003). Therefore, in the light of HIV infection, the risk associated with placental malaria appears to be independent of parity (van Eijk et al, 2003). HIV complicates diagnosis and management of malaria as a cause of anaemia at several levels.

HIV is itself a common cause of anaemia in pregnant adults and leads to several other causes of anaemia such as crytogenic tuberculosis (Lewis et al, 2005) and may make the treatment of malaria in pregnancy less effective. Therefore, due to the HIV pandemic, presumptive treatment to all women becomes necessary.

Evidence suggests that malaria could play a significant role in mother-to-child-transmission (MTCT) of HIV (Mwapasa et al, 2004; Ayisi et al, 2003), although this is by no means certain. Whitty et al (2005) argued that, because malaria and HIV co-infection is very common in Africa, even a small effect might be important. Malaria infection may lead to chronic inflammation of the placenta, which significantly raises HIV viral-load in both blood (Kublin et al, 2005) and breast milk. All three might theoretically increase the risk of HIV MTCT, especially if malaria occurs in the perinatal period. However, conflicting results are emerging from the trials conducted in this area so far. The interaction between HIV and malaria in pregnancy is potentially two ways; with each appearing to affect the other adversely (Whitty et al, 2005). HIV-infected women seem more likely to acquire malaria during pregnancy (van Eik et al, 2003, Ladner et al, 2003; 2002) and have relatively high parasite densities.

3.4 MALARIA IN PREGNANCY AND LOW BIRTH WEIGHT

LBW is a major risk factor for infant mortality in African populations affected by malaria (Guyatt and Snow, 2001b; McCormick, 1985). This is due to a combination of intra-uterine growth-retardation and pre-term delivery with primigravidae especially at risk from parasites that bind to chondroitin sulphate, and probably other receptors, on the placenta (Beeson et al, 2002). Pre-term delivery is delivery at less than 37 completed weeks of gestation. It is generally believed that where LBW figures are greater than 10%, the predominant cause is Intrauterine Growth Retardation (IUGR) and that the lower the overall LBW rate, the greater the proportion due to pre-term births (Villar and Belizan, 1982). The effect of LBW is devastating for both the foetus and the mother. Weight at birth has been considered the strongest predictor of infant survival and childhood health and development (WHO, 1980).

According to Gelbrand et al (2001), "In low and middle-income countries, 10-15% of neo-natal deaths are directly or indirectly attributed to low birth weight and pre-term delivery" (p25). Although reliable data on the magnitude and distribution of LBW is hard to come by (Gelband et al, 2001), a compilation of information on birth outcomes (de Onis et al, 1998) by WHO put the number of LBW infants born worldwide in 1995 at 20.5 million (Gelband et al, 2001). The malaria-related reasons for LBW babies are explained by the effect of malaria parasites on the placenta of the pregnant woman. LBW is partly due to parasitic sequestration in the placenta. Given the link between LBW and infant mortality, especially in developing countries, it is likely that placental malaria contributes to infant and perinatal mortality even where the malaria episode is successfully treated (Whitty et al, 2005).

Mild pre-term (32-36 weeks gestation) babies are at increased risk of respiratory distress syndrome, infection and neonatal and post-neonatal death (Dollfus et al, 1990; Doyle et al, 1999). Babies born earlier, before 32 weeks, are at high risk of severe morbidity and mortality even with specialised neonatal intensive care. They have a high risk of neonatal death and other complications compared with normal birth weight babies. Some of the LBW babies who are lucky enough to survive remain at risk of infection and impaired growth and development during their childhood.

3.4.1 Distribution of LBW

The distribution and case fatality rates of neonatal cases in general seen at the hospital level in developing countries vary, as indicated in Table 3.1. A study in Nigeria by Oruamabo and Ogunremi (1988) reveals that the case fatality rates (CFR) for ELBW, VLBW and LBW were 90%, 51.1% and 15.4% respectively. Another study in Port Harcourt by Okoji and Oruamabo (1992) reveals that of 1,509 singleton neonates, the prevalence of LBW ranged from 1.9% to 26.9% with the lowest percentage being the proportion of ELBW babies and the highest representing the proportion of LBW babies. The CFR ranged from 10.8% to 89.7%, with the lowest attributed to fatality rate of LBW cases and the highest to ELBW babies. The study concluded that high mean birth weight, longer gestation, and lower incidence of birth asphyxia were directly related to reduce fatality in infants. Van der Mei (1994) followed 567 LBW babies (less than or equal to 2000g) admitted during a seven year period in a hospital in the rainforest area of Ghana. LBW prevalence range was 5.5% to 7.3% with the lower representing the prevalence of LBW and the higher being ELBW. The study also reported that 26.8% of the babies died at the hospital (57% of them within the first 24 hours) and the average length of stay (ALoS) for non-fatal cases was 11.6 days. The CFR varied from 8.4% for those weighing 1751-2000g to 83.3% for ELBW. Van der Mei (2000) followed the growth and survival of 105 LBWs infants (1000-2000g), discharged during a four-year period, until they were between 4-9 years of age. The study found that 14% of the children did not return for age three follow-up, 10% of the remaining 90 died (five after the first three months); two could not be traced and another one died at 4-9 years follow-up. The details of LBW and their distribution are given in Table 3.1.

Table 3.1 Prevalence and case fatality rate (CFR) of LBW in Sub-Saharan Africa

Author(s)	Rates	Birth weight (%)				
		Extremely low (< 1000g)	Very low (1001g-1499g)	Low (1500g-2500g)	Normal (>2500g)	Sample size (where stated) (n)
Oruamabo and Ogunremi (1988)	Pre[1].	-	-	-	-	-
	CFR	90	51.1	15.4	-	-
Okoji and Oruamabo (1992)	Pre.	1.9	5.7	26.9	65.5	1,509
	CFR	89.7	53.5	10.8	5.3	-
Van der Mei et al (1994)	Pre.	7.3	-	5.5 (1.751-2kg)	-	567
	CFR	83.3	-	8.4	-	-
Van der Mei et al (2000)	Pre.	-	30.4	69.5 (1.5-2kg)	-	105 (1-2k g)
	CFR	-	-	-	-	-
Kambarami (2002)	Pre.	-	-	-	-	-
	CFR	-	-	39.4 (<1.8kg)	-	429
Were et al (2002)						
	CFR	100	32	22(1500-1999)	-	163
Simiyu (2003)	Prev.	-	5	33.4	-	308
	CFR	-	-	-	-	-

3.5 MALARIA IN PREGNANCY AND ANAEMIA

Anaemia is very common among women of reproductive age in developing countries and the estimated figures for Africa are that, two-thirds of all pregnant and half of non-pregnant women are anaemic (Winikoff, 1988). Gelband et al (2001) have described anaemia as the most prevalent contributor to maternal mortality and morbidity. However, information on the number of deaths averted through preventing anaemia is uncertain. Anaemia is more common in pregnant women than their non-pregnant counterparts. This is due to the increase in quantity of fluid in the circulatory system (plasma) during the second trimester as well as the increased demand on iron and folate stores (WHO, 2002).

The diagnosis and management processes of anaemia and malaria in pregnancy for semi-immune women are often not clear-cut (Whitty et al, 2005). Because placental malaria can lead to anaemia with few other symptoms and few clues in the laboratory tests, an afebrile woman with parasites seen on the peripheral blood film may have placental malaria as either a major contributing factor or the only cause for anaemia (Whitty et al, 2005). Even where parasites are seen, it does not necessarily mean that malaria is the only cause of the anaemia because anaemia in developing countries often has other causes (van den Broek, 2003).

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[1] Prevalence rate.

Maternal deaths from all causes have been put at half a million per year worldwide, but 99% are said to occur in developing countries (Shulman et al, 1999). Severe maternal anaemia during pregnancy is a risk factor for maternal mortality and is responsible for 8-20% of such deaths in hospitals in Sub-Saharan Africa (SSA) and 11-13% in community-based studies (MacLeod and Rhode, 1998; Shulman et al, 1999). However, Shulman et al (1999) questioned the link between maternal death and anaemia on the basis that haemoglobin tests are not normally performed in places where severe anaemia is prevalent and the retrospective diagnosis of anaemia as a cause of death is difficult. It has been estimated that malaria-related anaemia causes an estimated 10,000 maternal deaths each year in Africa (WHO, 2002) and there is evidence that pregnant women with severe anaemia are several times more likely to suffer from pregnancy-related deaths than those without it (Gelband et al, 2001). The widespread nature of anaemia in developing countries leads to consequences beyond pregnancy. Evidence from Kilifi District Hospital in Kenya showed that 36.5% of severely anaemic women have LBW babies compared with 15.7% of other women (Shulman et al, 1999).

The numerous causes of anaemia during pregnancy include, nutritional deficiencies (Dreyfuss et al, 2000), haemoglobinopathies, hookworm infection (common amongst those in farm work), low iron bioavailability, folate and vitamin B-12 deficiency, and *Plasmodium falciparum* malaria especially in primigravidae who have a higher prevalence and density of parasitaemia. The contribution of malaria, however, has been singled out as substantial and unchallenged (Fleming, 1987; WHO, 2002). Since it is almost impossible to rule out placental malaria as a cause of anaemia in semi-immune women, it has been recommended that anti-malarial drugs should be given to all cases of severe anaemia in pregnancy, even where other causes of anaemia can be proven (Whitty et al, 2005).

3.5.1 Distribution of anaemia

As indicated in Section 3.4, anaemia has several causes. This section seeks to show the distribution of anaemia into mild, moderate, severe, and very severe cases regardless of cause. This is so because it is difficult to obtain data on anaemia that is attributable to only malaria in pregnancy. A prospective study of the prevalence of anaemia in pregnancy amongst 279 first-time attendants of antenatal care in Ethiopia found an overall prevalence rate of 41.9%; 35.9% for urban and 56.8% for rural areas (Desalegn, 1993). Most of the women (74.3%) had moderate anaemia and only 2.5% had severe anaemia. Another study of 435 pregnant women attending an antenatal clinic at University Clinic in Benin City in Nigeria found moderate and severe anaemia cases at 20.7% and 2.8% respectively (Ogbeide et al, 1994).

Shulman et al (1996) undertook a study to determine the prevalence and aetiology of anaemia in pregnancy in Coastal Kenya, to establish locally important causes and enable the development of appropriate intervention strategies. Of 275 women attending an antenatal clinic, prevalence of anaemia for all parities was 75.6%. Of these, severe anaemia represented 9.8%. Anaemia by parity showed that severe anaemia for primigravidae and multigravidae was 15.1% and 7.9% respectively.

Severe anaemia was found to be twice as common in women with peripheral malaria parasitaemia when compared to those without. Van der Broek et al (2000) shows that the prevalence of anaemia in pregnancy in Southern Malawi was 57% for urban women and 72% for rural women. Of these, 3.6% of urban and 4% of rural cases was severe. Primigravidae were found to be at slightly higher risk of overall and severe anaemia. A cross-sectional study in Bobo-Dioulasso, Burkina Faso revealed that 66% of the women were anaemic. Of these, 30.8% were mild, 33.5% moderate, and 1.7% severe (Meda et al, 1999). Prevalence amongst HIV-infected women was highest at 78.4% compared to 64.7% for the non-infected. The level of severe anaemia in Kisimu, Kenya amongst 1,455 women was 22% (Ondimu, 2000). The details of anaemia and their distribution are given in Table 3.2.

Table 3.2 Prevalence of anaemia in Sub-Saharan Africa

Author(s)	Category	Anaemia (%)					
		Very Severe	Severe	Moderate	Mild	All cases	Sample size (where stated) (n)
Desalegn (1993)	-	-	2.5	74.3	-	41.9	279
	Urban	-	-	-	-	35.9	-
	Rural	-	-	-	-	56.8	-
Ogbeide et al (1994)		-	2.8	20.7	-	-	435
Shulman et al (1996)	Primi[2] and Multi[3]	-	9.8	-	-	75.6	275
	Primi		15.1				-
	Multi	-	7.9	-	-		-
Meda et al (1999)		-	1.7	33.5	30.8	66	-
van der Broek (2000)	Urban	-	3.6	-	-	57	-
	Rural		4	-	-	72	-
Ondimu (2000)	-	-	22	-			1,455

[2] Primigravidae.
[3] Multigravidae.

3.6 PREVENTION AND CONTROL OF MALARIA IN PREGNANCY

Several malaria prevention and control approaches have been advanced. These involve interventions during pregnancy, treatment of complications during birth (intrapartum) and after birth (postpartum) and early neonatal care. Among all the available measures, the two common approaches to the prevention of malaria in pregnancy are insecticide treated nets (ITNs) (Bradley et al, 1986; Alonso et al, 1991) and Intermittent Preventative Treatment (IPT). ITNs have been recognised as the main tool for reducing malaria in pregnancy (ter Kulie et al, 2004, Lengeler, 2004). According to Whitty et al (2005), ITNs are one of the cheapest, simplest and most effective methods of preventing morbidity and mortality from malaria in Africa.

Although ITNs are generally believed to be good at protecting against malaria, there is no guarantee that women may not get malaria at some stage during pregnancy, which may not be detected clinically. Despite the fact that the results of initial studies of the impact of ITNs on the outcome of pregnancy produced mixed results, a large trial in Western Kenya has demonstrated convincingly that ITNs can reduce both maternal anaemia and the incidence of LBW even in an area of very high transmission (ter Kuile et al, 2003a; 2003b).

IPTp is WHO recommended method of preventing malaria in pregnancy by giving at least two doses of SP to all pregnant women regardless of their malaria infection status (Worrall et al, 2007). Previous studies conducted with pregnant women have shown that by preventing or treating malaria in pregnancy, anaemia can be reduced and birth weight improved. A study in The Gambia using fortnightly maloprim, conducted by Greenwood et al (1989), found improved birth weight and haemoglobin in primigravidae and women of at least gravidity five but not in other parities. The result of a trial with chemoprophylaxis conducted in women of all parities in Nigeria found an improvement of birth weight for women who received chemoprophylaxis with pyrimethamine compared with placebo, but the greatest effect on birth weight was found in primigravidae and women of at least gravidity four (Morley et al, 1964).

A study in Malawi (Steketee et al, 1996c) found an improvement in birth weight in women of all parities who received mefloquine compared with chloroquine. The frequency of LBW due to placental infection in the same country from 1988-1991 was 30.5% for primigravidae, 20% for secundigravidae and 14% in those of at least gravidity three (Steketee, 2001). Weekly prophylaxis with chloroquine has been the first preventive strategy in many countries but has not been very acceptable due to its bitter taste and the seemingly frequent weekly dose (Heymann et al, 1990).

Studies undertaken in Kenya and Malawi to address the effectiveness of intermittent treatment with anti-malarials, given between 16 and 34 weeks gestation, have demonstrated that intermittent treatment with Sulphadoxine-Pyrimethamine (SP) given in the second and third trimesters can reduce placental parasitaemia in primigravidae and secundigravidae (Schultz et al, 1994). It can also reduce severe maternal anaemia in primigravidae (Shulman et al, 1999), and improve birth weight in primigravidae and secundigravidae (Parise et al. 1998). Giving SP as IPTp two or three times to all pregnant women in highly endemic areas — irrespective of whether women have malaria parasites in their blood or not — could reduce maternal anaemia and increase birth weight (Shulman et al, 1999; van Eik et al, 2004; Kayentao et al, 2005; Rogerson et al, 2000, Challis et al, 2004).

Trials have also shown that malaria prophylaxis improves birth outcomes in pregnant women living in highly endemic areas (Geelhoed et al, 2001; Ndgomugyenyi et al, 2000). However, the main difficulty is implementing this on a wider scale (Greenwood, 2004). Evidence supports the fact that the effect of IPTp is greatest in the first pregnancy, possibly because primigravidae are comparatively more vulnerable to malaria as explained by Whitty et al (2005). Moreover, trials that confirmed the efficaciousness of IPTp with SP took place in settings where rates of resistance to SP were moderate or low. However, the effect of SP as IPTp is reduced in those women with HIV co-infection.

It is now national policy in Kenya and Malawi, as well as Tanzania, to give SP as IPTp. There were recommendations that this could be done through existing antenatal clinics (WHO, 2002). The 20th Malaria Expert Committee designated using an efficacious, preferably single-dose, anti-malaria drug as the preferred approach to reduce the adverse consequences of malaria in pregnancy (WHO, 2002). Antenatal clinics have been identified as the best institutions for these interventions (Schultz et al; 1995; Meek and Webster, 2001; Wolfe et al, 2001; WHO, 2002).

Although the benefits of IPTp on women of lower parity are not in doubt, evidence of the benefit of preventative strategies in multigravidae remains unclear. One of the reasons for this is most of the previous trials limited recruitment to primigravidae, secundigravidae or both, and there are no known large studies on IPTp for women of more than gravidity two. Pregnant women and children who have not yet developed immunity are at high-risk of malaria in endemic areas of Sub-Saharan Africa (Clarke, 2001). Therefore, protection of this group to reduce the risk of exposure to mosquito bites and malaria constitutes an important part of malaria prevention.

Malaria prevention depends largely on the level of individual and community awareness of the danger of malaria, time and income available for prevention activities and education of individuals (Koram, 1993). Koram (1993) mentioned other measures such as screening houses, building of houses away from breeding grounds, proper disposal of cans and filling of pits around dwellings, clearing vegetation along edges of water bodies, and clearing ditches with a view to reducing the suitable breeding grounds for mosquitoes. In The Gambia, both expatriate and the local population have used bednets for over a century (Aikins et al, 1993; Greenwood and Pickering, 1993). A study in rural Gambia on the measures families take against mosquito-bites revealed that 90% used bednets (Clarke, 2001). Other protection measures combined with the use of bednets include local repellent 'churai' (55%) and mosquito coils (22%) (Aikins et al, 1993). Churai is a local insence, which women use in houses to repel mosquitoes. IPTp on the other hand has not been a policy in The Gambia prior to 2003.

3.7 ECONOMIC EVALUATION OF MALARIA INTERVENTIONS IN DEVELOPING COUNTRIES

The objective of this section is to review the available empirical literature on economic evaluations of malaria in pregnancy in SSA. The studies included involve economic evaluations, which involve the assessment of alternative treatments and control of malaria in pregnant women. The results are expressed in United States Dollars (USD). Seven peer-reviewed studies that have examined the cost-effectiveness of chemoprophylaxis or IPTp include those done by Heymann et al (1990), Helitzer-Allen et al (1993), Schultz et al (1995), Schultz et al (1996), Goodman et al (1999b), Wolfe et al (2001) and Breman et al (2006) (see Table 3.3). By using a decision-analysis model to assess the cost-effectiveness of anti-malarial intervention on a hypothetical cohort of 10,000 women in Malawi, Schultz et al (1995) reported a cost-effectiveness ratio of $9.66 (1992 prices) per case averted. Other less cost-effective regimens were $62.01 and $113.05 per case of LBW averted. The number of cases of LBW prevented by two consecutive doses of Sulphadoxine-Pyrimethamine (SP/SP), a dose of Sulphadoxine-Pyrimethamine followed by a dose of Chloroquine (SP/CQ) and two consecutive doses of Chloroquine (CQ/CQ) regimens were 205, 59 and 30, respectively, with a cost per death averted of $81, $522 and $950. Another study in the same setting reported a cost per LBW death averted of $75 for two treatment doses of SP, compared with $481 for an initial SP dose followed by weekly CQ or $542 for two doses of chloroquine (Schultz et al, 1996).

Table 3.3 Summary of economic evaluations of malaria in pregnancy in Sub-Saharan Africa

Author(s)	Areas studied	Intervention	Cost per LBW case averted	Cost per LBW death averted	Cost per DALY averted
Heymann et al (1989)	Malawi (1986 prices)	-	$10.87	-	-
Helitzer-Allen et al (1993)	Malawi	3 different intervention to increase compliance to chemoprophylaxis	CQ + OHE-$1.67 CQ + NHE-$1.27 CCQ +OHE-$1.20 CCQ +NHE-$1.48	-	-
Schultz et al (1995)	Malawi, 1992 costs from other studies	Antenatal treatment and chemoprophylaxis SP/SP SP/CQ CQ/CQ	$9.66 $62 $113	$81 ($79-352) $522 ($212-812) $950 ($317-951)	-
Schultz et al (1996)	Malawi	SP/SP, SP/CQ CQ/CQ	-	$75 $481 $542	-
Goodman et al (1999b)	SSA	2 doses (SP)	-	-	$14-$29
Wolfe et al (2001)	Kenya (HIV prevalence at least 10% and less than 10%	HIV prevalence <10% (2 doses)	$11	-	-
		HIV prevalence >10% (monthly)	$14	-	-
Breman JG et al (2006)	SSA	IPTp with SP including additional doses for HIV positive women	-	-	ICER= $13 per DALY averted (range $9-21) Total cost = $24 per DALY averted (range 16-35

In Malawi, Heymann et al (1990) chose four antenatal sites, two in a seasonal malaria area, and two in an area where malaria was present throughout the year, in order to assess compliance. For the 802 participants enrolled, protective efficacy for parasitaemia was 23% on first visit and 8% on return and the cost of preventing *Plasmodium falciparum* was $10.87 per LBW case averted (1986 prices). Poor compliance due to bitter taste and short frequency of taking the dose (weekly) were given as the key reason for the high cost. If compliance was raised to 80%, the cost would be $1.09 per case prevented. Helitzer-Allen et al (1993) evaluated the cost-effectiveness of three different interventions (each comprised of a health education message and an anti-malarial drug) designed to increase compliance to the chemoprophylaxis programme compared with the base case. Compliance rates were 57%, 87%, 91% for interventions 1-3, respectively, against the base case of only 25%. The cost per compliant woman was $2.15 with the original practice.

This subsequently dropped to $1.64 per compliant woman for the new health education campaign alone and to $1.55 for the new health education message with the coated tablets. The costs per LBW case averted are shown in Table 3.3. A study comparing three different IPTp regimens with febrile case management using SP, for a hypothetical cohort of 10,000 pregnant women in Kenya, revealed that a two-dose SP regimen in an environment where HIV prevalence is 10 or less is a cost-effective strategy for preventing LBW, at $11 (two doses) and $14 (monthly doses) per death averted (Wolfe et al, 2001).

Each of the above four studies were summarised in a review by Goodman et al (1999a) and the fifth in a recent review by Worall et al (2007). The review by Goodman and her colleagues aggregated the available data to derive the incremental cost-effectiveness of incorporating an intervention (i.e. SP intermittent treatment) into an existing structure of antenatal care, estimated at between $4-29 per DALY averted. The average cost-effectiveness in a very low-income country with high transmission was estimated at $13 per DALY averted. Of particular relevance to this study was the finding that using intermittent treatment rather than weekly chemoprophylaxis improves compliance, and in turn, cost-effectiveness. The findings of Breman et al (2006) summarised by Worall et al (2007) is not different from those of Goodman and colleagues.

Although attempts were made by these studies to shed light on issues of the cost-effectiveness of alternative interventions for controlling maternal malaria, the sample sizes for some studies were too small to reliably generalise their finding to other settings. These studies included all pregnant women and were not restricted to primigravidae or multigravidae. Except for Goodman et al (1999a), all of the studies estimated cost per case averted and the costs considered were mainly incurred by the provider. In all cases, no costs were estimated for patients.

3.8 VARIATIONS IN COST-EFFECTIVENESS OF INTERVENTIONS BETWEEN MULTIGRAVIDAE AND EARLIER PREGNANCIES

Malaria in pregnancy is less severe as pregnancies progress, so in theory an intervention that has a significant effect in a first pregnancy may not have an effect in a fourth or fifth. Empirical evidence in eight countries in SSA showed that primigravidae had higher prevalence of peripheral and placental malaria infection compared to multigravidae (see Section 3.3 for details). The difference between those infected in terms of mean haemoglobin levels were more marked in primigravidae than multigravidae.

No reasons have been advanced for this but it is believed that immunosuppression is more marked in primigravidae and also the possibility that protective immunity could be acquired in the placenta through malaria infection during the first pregnancy thereby reducing susceptibility in subsequent pregnancies (see Section 3.3 for details). Studies in Malawi report that IPTp with SP reduces LBW in primigravidae but not in multigravidae. The result of a trial with chemoprophylaxis for women of all parities in The Gambia and Nigeria found an improvement of birth weight for those who received chemoprophylaxis with primigravidae (see Section 3.5 for details).

However, the greatest effect on birth weight was found in primigravidae and women of at least gravidity four. In light of the differences in malaria prevalence and effectiveness of IPTp according to the number of pregnancies, the cost-effectiveness is also likely to be different for primigravidae, secundagraviade and multigravidae. Given that many pregnancies in Africa are to multigravidae women, it may be cost-effective to have a programme for first and second pregnancies, which is not cost-effective for subsequent pregnancies.

Although IPTp with SP is recommended for women of all gravidae, there is however little evidence to support its use in multigravidae as there is no known previous trial that has specifically addressed the effectiveness of SP as IPTp for this group of women. While IPTp with SP has been shown to be highly cost-effective for primigravidae, the effect on cost-effectiveness of introducing to multigravidae remains untested.

3.9 SUMMARY

This chapter reviews literature on malaria in pregnancy and its effects on LBW and anaemia. The distribution of LBW and anaemia has also been outlined. In terms of economic evaluation in this area, relatively few published studies are available. Many of the existing studies suffer from small sample sizes, which limit the generalisability of results to other settings. Almost all the studies took the provider perspective and omitted important costs to patients and their families, the inclusion of which could change the policy conclusion. Moreover, as pointed out by Goodman et al (2000), many of the studies narrowly defined cost as only drug costs and failed to take into account additional costs normally incurred by health services with respect to service delivery. All the studies reviewed focused on infants in terms of cases, deaths or DALYs averted from LBW. Since anaemia has been cited as one of the major causes of maternal mortality and morbidity, it will be revealing to consider the effects of interventions on the mothers too.

The chapter ended by outlining why interventions may be different in multigravidae than earlier pregnancies. The difference was mainly attributed to immunosuppression being more marked in primigravidae than multigravidae and the possibility of acquiring protective immunity through malaria infection in the first pregnancy, thereby reducing susceptibility in subsequent pregnancies. It ended by indicating that IPTp with SP was highly cost-effective for primigravidae, while its effect on cost-effectiveness for multigravidae was unproven.

CHAPTER 4: COUNTRY PROFILE: THE GAMBIA

4.1. INTRODUCTION

The main purpose of this chapter is to provide an overview of the study country, The Gambia, followed by a detailed description of the IPTp trial settings of the country's North Bank East (NBE) and Lower River Division (LRW). The chapter is divided into six sections. Section 4.2 gives the physical (geographical and climatic) and demographic profiles of the country. Sections 4.3, 4.4 and 4.5 are devoted to The Gambia's general economic situation, showing trends and indicators with an emphasis on poverty and gender situations and their impacts on women. Section 4.6 looks at the health system in general, highlighting the health infrastructure including antenatal and obstetrics care and the health care financing system. Section 4.7 describes the study location of NBE and LRD and gives reasons for the selection of these study sites. The chapter ends with a brief summary in Section 4.8

4.2. PROFILE

The Gambia is a small sovereign state in West Africa with a land area of 10, 689 square kilometres. The country varies in width between 42 kilometres near the mouth of river Gambia to 24 kilometres further upstream and stretching about 480 km in length. As illustrated in Figure 4.1, The Gambia is located at the west coast of Africa between latitudes 13.0N and 13.7N and longitudes 13.7W and 16.0W. The country is divided into two by the River Gambia that runs the entire length, from the Futa Jallon highlands in the Republic of Guinea to the Atlantic Ocean. The river, including its swamps and creeks, covers one third of the surface area of the country (approximately 2075 sq. km). Its flow is low during the dry season bringing about saline intrusion up to 248 km upstream and the saline interface is flushed down to 150 km during the rainy season. The Gambia is bordered on all sides by the Republic of Senegal, except for the western part, which faces the Atlantic Ocean.

The climate is typically Sudano-Sahelian with a long dry season from November to May and a short rainy season from June to October. During the dry season, Harmattan winds blow from the Sahara desert, resulting in cool but dusty weather. There has been a general decline in rainfall over the past two decades, but improvements have been recorded in the latter part of the 1990s. Average annual rainfall ranges from 800mm in the east to 1,700mm in the west. The maximum temperature in the coastal area during the rainy season is about 32°C with daily minimum temperature ranging from 18-24°C (WHO, 2003; UNDP, 1999).

Figure 4.1 Map of the Gambia depicting the study areas of NBE and LRD
Source: Financial Sustainability plan of EPI Programmes, (DoSH, 2003).

The daily maximum temperature varies from 10°C during the dry season to 45°C in the rainy season and the humidity for the two periods ranges from 40-80%. The land is mainly low lying and flat, varying from sea level at the coastal area to a maximum elevation of 36m in the interior. The country is covered with tropical forest, mangroves and savannah woodland along the river and the western part (WHO/DoSH, 2005). The nature of the climate makes The Gambia attractive to tropical diseases such as malaria.

4.2.1. Politics and demographic profile

The Gambia attained internal self-government in October 1963 and full independence on 18 February 1965. Republican status was gained in 1970 with Sir Dawda Kairaba Jawara as the first President, a post he held until July 1994 when he was overthrown through a military coup. The country was later returned to civilian rule in 1996.

There are five administrative divisions, Western, Lower River, North Bank, Central River and Upper River; each administered by a Divisional Commissioner now called Governor (Figure 4.1). In addition to the five divisions, there is Kanifing municipality, which is called Kombo St. Mary's division and Banjul. The administrative decentralisation of the country is currently on the drawing board and most of the reforms that need to go with it are yet to be effected. The 1993 health reforms resulted in the devolution of administration to six Divisional Health Teams (DHTs). However, one fundamental aspect lacking with the DHT administration is autonomy with respect to budgetary matters, which are still centralised.

The provisional results of the 2003 National Population and Housing Census of The Gambia put the total population at 1,350,032 (see Table 4.1), with an annual growth rate of 2.8% (CSD, 2003). This was a reduction from the 1993 growth rate of 4.2%. The gender mix is roughly equal, with 49.6% of the population male. Recent figures are not available but foreign nationals accounted for 13.7% of the population in 1993. The high in-migration was due to instability in the sub-region. The population density was estimated at 127 persons per square kilometre in 2003 (CSD, 2006). The Greater Banjul Area, which comprises the capital, Banjul, the adjoining Kanifing municipality and surrounding towns, has 52% of the population. The distribution of the 1993 population by DHT shows that 29% lived in the Western Division, 5% in the Lower River Division, 13% in the North Bank Division (6% in North Bank West and 7% in North Bank East), 14% in the Central River Division and 13% in the Upper River Division. Twenty six percent (26%) of the population lived in urban areas whilst the rest live in rural areas (UNICEF, 2004). According to the WHO (2003), the life expectancy for the total population of The Gambia was 57 years in 2003; 56 years for males and 59 for females.

Table 4.1 Population and number of health facilities by health division

Health Divisions	Population (000)	Hospital	Major Heath Centre	Minor Health Centre	Dispensary	PHC
Western Division (WD)	75,0225	2	2	4	4	127
Lower River Division (LRD)	72,546		1	2	1	64
North Bank West Division (NBD)	72,806		1	1	1	64
North Bank East (NBE)	85,525	1		1	2	43
Central River Division (CRD)	185,897	1	1	2	5	89
Upper River Division (URD)	183, 033		1	2	3	60
TOTAL	**1,350,032**	**4**	**6**	**12**	**16**	**447**

Source: Adapted from 2003 Census report & Public Expenditure Review (DoSH, 2001a).

4.2.2. Ethnicity and religion

The main ethnic groups in The Gambia are Mandinka (35.65%), Wolof (13.23%), Fula (17.02%), Jola (9.38), Serahuli (7.3%), Serere (2.26%), Manjago (1.6%), Aku (0.73%) and Bambara (0.44%) (CSD, 1993). Ninety-five percent of the population practise Islam as their religion whilst the remaining 5% comprises mainly Christians and other faiths. The typical African extended family system is very apparent in The Gambia and families normally live in neighbouring houses in close proximity of a 'compound'. A compound is a congregation of houses often fenced off from farming and grazing areas (WHO/DOSH, 2005).

4.2.3. Fertility and mortality

The total fertility rate (TFR) is at 5.1 children per woman, and has declined by around 16% from 6.04 in the last three decades (1993-2003) (CSD, 2004). The Crude Birth Rate has decreased from 46/1000 in 1995 to 36/1000 in 2003. This rate is expected to drop further due to the high contraceptive prevalence rate experienced recently (i.e. 12% in 1990, 17.5% in 2001). The mortality trends show a downward movement with the crude death rate estimated at 13 per 1000 persons in 2003, down from 19 per 1000 persons in 1993. The high fertility rate and low life expectancy have resulted in a very youthful population structure. From the 1993 census, nearly 45% of the population was below 15 years and 19% between the ages of 15-24 years (CSD, 1993). Those aged 0-14 constituted 44% of the total population (45% of males and 44% of females were under 15 years). The 0-4 year age bracket constituted 17% of the population for the period 1973-1993.

4.3. THE ECONOMY

The Gambia is one of the least developed countries in the world with a GDP per capita estimated at $318 (UNDP, 2004). The country experienced a serious economic downturn between 1975 and 1985, with the rate of real GDP growth averaging below 3% per annum. The performance of the economy worsened during the latter part of this period, such that by early 1985, the underlying internal and external imbalances had assumed major proportions owing to a combination of adverse factors such as expansionary financial policies, inappropriate exchange rates and other pricing policies (WHO/DoSH, 2005).

In order to arrest the situation, in 1985 the government adopted a comprehensive medium term Economic Recovery Programme (ERP). The policy measures, although effective in reversing the declining economic trend, also led to a significant reduction in government expenditure on health and education, which had serious consequences for low-income earners. Adjustments had to be made to ameliorate the conditions of the poor, hence the launching of Programme for Sustained Development (PSD), which aimed at consolidating the economic gains of the ERP as well as focusing on concerns of the vulnerable groups.

The average GDP per capita growth rate from 1990-2003 averaged 0.1% and the inflation rate was estimated at 17.6%. The total external debt for the same period was $615 million. The exports for the year 2003 totalled $102 million and imports were $116 million leading to a Balance of Payment (BoP) deficit of $14 million. The Gambian economy is largely dependent on agriculture, which employed around 57% of the labour force and accounted for about 25% of GDP during the period 1990-2003.

Agriculture is the source of livelihood for around 80% of the rural population. Since the 1990s, the service sector — including tourism — has emerged as a potential source of rapid growth for the economy, surpassing agriculture and contributing around 64% of GDP during the period. The industrial sector, made up of manufacturing, construction and utilities sub-sectors, remained at 11% of GDP (Personal Communication, Director of Policy Analysis, The Gambia).

4.4. POVERTY

According to the National Household Poverty Survey Report, 69% of the population, mainly women, lives below the poverty line (CSD, 1998), with 59% of the population living on less than $1 a day. The income per capita is four to five times higher in the urban than the rural population and extreme poverty more than doubled between 1992 and 1998 in all divisions (UNDP, 1999). More than half (51%) of Gambians lived in abject poverty in 1998 and the incidence of extreme poverty was highest among the groundnut farming socio-economic group. Lower River, Central River, and Western Divisions are the poorest and extreme poverty is highest in Upper River followed by Lower River and North Bank Divisions. Poverty is a fundamental cause of household food insecurity and consequent under-nutrition (CSD, 1998).

An International Labour Organisation study found that 3% of urban households and 38% of the urban population were food poor, while in rural areas, 37% of households and 54% of the population were also categorised the same. The adult literacy rate (15 years and above) was 37%, with men at 44.5% and women at 26.9% (WHO/DoSH, 2005). The enrolment ratio for Lower and Upper Basic Education, including Madrassa (Islamic schools), was 75% and 72% respectively. In rural areas, 20% of men and 6% of women were literate. The gross enrolment ratio at primary school for girls was 75% from 1998-2002 and the ratio for boys for the same period was 82% (WHO/DoSH, 2005).

4.5. GENDER ISSUES

Traditional roles of women are still recognised in The Gambia and gender inequality in the society is largely unchallenged, having been reinforced by illiteracy and cultural practices (WHO/DoSH, 2005). Many traditional customs have a gender element with implications for the health of pregnant women and teenage girls, particularly in rural areas. Early-age marriages and low-age at first birth are both contributing factors to high fertility levels, lower rate of girls' education and poor participation of women in economic activities. As a result, when compared to boys, girls have limited opportunities to proceed with their education or to access various formal and informal avenues (WHO/DoSH, 2005).

Apart from early marriage, traditional and religious misconceptions of family planning, food taboos, high illiteracy, low status of women and harmful traditional practices such as female genital mutilation continue to have a negative impact on women (WHO/DoSH, 2005).

4.6. HEALTH SYSTEM

The health policies in The Gambia since 1979 have placed emphasis on the Primary Health Care strategy (PHC). The current National Health Policy, entitled "Changing for Good", was formulated in 2001 and the vision of the policy is the attainment of accessible quality health care for the Gambian population (DoSH, 2001). Health services are delivered in facilities funded by government, non-governmental organisations (NGOs) and private practitioners. There are 38 public health facilities at secondary and tertiary levels and 48 private/NGO facilities in The Gambia. Although no data are available on the proportion of health services delivered by each of these groups, 30% of the public health care facilities and 73% of private/NGO facilities are located within the Divisional Health Team (DHT)-Western (i.e. Greater Banjul area which is mainly urban, and Brikama) (DoSH, 2001). However, it must be emphasised that private health facilities are smaller than public facilities. In addition, a large number of pharmacies, drug sellers and traditional medical practitioners exist throughout the country.

The public health service delivery structure in The Gambia is a three-tier system based on the primary health care (PHC) strategy, with emphasis on preventive rather than curative care and with a clear-cut referral system. There are four hospitals, 34 secondary level facilities and 447 health posts spread throughout the country (see Table 4.1). Access to antenatal services is good compared to many other Sub-Saharan African countries but still remains irregular and low compared to developed countries (DoSH, 2001). The average travel times to and from public health facilities are 72 minutes on foot, 80 minutes by vehicle, 243 minutes part foot and part vehicle, 82 minutes by cart and 54 minutes using other modes of travel (DoSH, 2001). The longest time taken to reach health facilities on foot was 97 minutes in Western Division (part urban and part rural) which translates into an average walking time of less than 50 minutes each way. It takes 62 minutes to walk to and from health facilities in exclusively urban areas (Banjul and Kanifing Municipal Council (K.M.C)), 57 minutes in exclusively rural areas (DoSH, 2001). Ninety-four percent of women attend antenatal care at least once, with an average of 3.4 attendances for the entire duration of a pregnancy (Cham, 2003). The multiple roles and time constraints faced by women compared to men, potentially deter them from using health services (DoSH, 2000).

The primary level or Village Health Services (VHSs) are made up of 447 PHC villages with health posts and form the lowest level of health care delivery. Generally, PHC villages in The Gambia have on average 400 inhabitants and are staffed by a trained Village Health Worker (VHW) and a Traditional Birth Attendant (TBA). While the VHW maintains the supply of essential drugs, provides outpatient care, makes home visits and carries out health education, the TBA conducts deliveries, and identifies and refers at-risk mothers to the nearest health facilities (DoSH, 2001). Both VHWs and TBAs are supervised by a Community Health Nurse (CHN). Each CHN supervises at least five PHC villages and the CHNs are themselves supervised by the head of the nearest health facility and the DHT. Between 60-80% of the population at the divisional level live within the catchment area of VHS and 90% live within a radius of 7.5 km of a health facility, while 80% live less than an hour's travel time from the facility (DoSH, 2001). The majority of villages in the Western division are PHC villages, while only one in six are in North Bank settlements such as North Bank Division, northern parts of Central River Division (CRD), and Upper River Division (URD). These settlements have poorer access to health facilities, which is further exacerbated by poor transport infrastructure (DoSH, 2001).

Establishing a settlement as a PHC village requires the village to have a population of at least 400, identification of VHW and TBA by the villagers, setting up of a Village Development Committee (VDC) and provision of the initial drugs supply worth D500 by the DoSH. Therefore, the delay in the expansion of PHC facilities in all villages throughout the country is hampered by the small size of most of the villages and the complexities in managing big towns. Further, having more PHC villages would entail the training of more CHNs to supervise them, with attendant investments in motorcycles and supervisory vehicles. It may also require building more health facilities for referrals since PHCs are supposed to be close to such health facilities.

One of the main problems at the community level is the inability of communities to organise themselves into groups. Finally, with the coming of the Cuban Technical Assistance Programme, the staff posting is not strictly adhered to as doctors and qualified nurses are posted to lower level facilities including PHC facilities. There has been a 67% increase in the number of doctors between 1997 and 2001, which led to a large number of these doctors being posted at every level in the public health system (DoSH, 2001). The same report showed that one in 10 doctors work at the primary level in villages.

Secondary level services (Basic Health Services) comprise six major health centres (UNDP, 1999), 12 minor health centres and 16 dispensaries (DoSH, 2001). Centres are classified according to the type of health services they provide. Amongst them, major health institutions provide the highest standard of care and are staffed by doctors, State Registered Nurses (SRNs) and State Enrolled Nurses (SENs) as well as other technical staff such as laboratory technologists and pharmacists. Minor health centres have a similar staff profile as major health centres but without medical doctors. Dispensaries are staffed by SENs and CHNs. Complicated illnesses are referred from dispensaries and minor health centres to the major health centres and eventually to hospital if need be. Although the number of secondary care facilities has remained stagnant over the past 15 years, many have been upgraded during the period. Four public hospitals currently provide tertiary services. These are; Royal Victoria Teaching Hospital (RVTH), Bansang Hospital, Armed Forces Provisional Ruling Council Hospital (AFPRCH) and Bwiam Hospital. There are also a couple of other private and NGO hospitals. The construction of one more hospital in Serrekunda is at an advanced stage.

Forty percent of the Department of State for Health (DoSH) labour force, including nearly 80% of its doctors and the majority of qualified SRNs and SENs, are employed in tertiary facilities. While almost all nurses and environmental health officers in the country are Gambians, less than 10% of the doctors are nationals of that country (DoSH, 2001). Almost all the medical doctors working in The Gambia come from Nigeria, Cuba and Egypt through bilateral assistance programmes. In addition to government health facilities, there are many NGOs participating in the provision of health care in The Gambia. Some are faith based, while others are local branches of international NGOs which together run 15 health facilities, including Medical Research Council (MRC) facilities in different parts of the country. Unlike NGO facilities, the bulk of the private health facilities are concentrated mainly in the western area.

In terms of public-private mix, the DoSH has outsourced the provision of transport for its activities to an international NGO called Riders for Health (RFH), which is paid an agreed cost-per-kilometre for use of health vehicles (WHO/DoSH, 2005). Traditional medicine is increasingly being recognised, and 4% of the people who reported ill/injured two weeks prior to the 1998 National Household Poverty Survey consulted traditional healers (CSD, 1998). This prompted health authorities to formally recognise and incorporate traditional medicine into the new health policy. Use of public outpatient health services were 33% hospital and 67% basic health services. The corresponding proportions for public inpatient (IP) services were 44.8% for hospitals and 55.2% for basic health facilities (DoSH, 2001).

Malaria is the number-one cause of morbidity and mortality in The Gambia (DoSH, 2001). According to a report on selected health indicators, the top seven causes of morbidity and mortality in under-fives are malaria, pneumonia, anaemia, malnutrition, sepsis, low birth weight, trauma and burns (DoSH, 2001). About 40%-60% of the total outpatient department (OPD) consultations in 1999 were due to malaria, while acute respiratory tract infections accounted for 25% (DoSH, 2001).

The infant mortality rate was 84/1000 live births in 2001 (NaNA/MRC, 2001) and 75 in 2003 (CSD, 2006). The under-five mortality rate was 123/1000 in 2003. The child immunisation rate was above 80% in 2003. The country has been certified as polio-free by the Africa Certification Committee. Approximately 19% of all newborns had a low birth weight (less than 2500gm) (DoSH, 2001) and a survey conducted by the National Nutrition Agency (NaNA) reported that only 3.7% of children under five were within the expected weight for height (NaNA/MRC, 2001).

The nationwide survey on the prevalence of Vitamin A and iron deficiency in women and children in The Gambia found that 73% of pregnant women showed moderate anaemia and 5% showed high-risk anaemia (NaNA/MRC, 2001). Iron deficiency anaemia was common among pregnant women and was said to be a major contributor to the high maternal mortality rate. The maternal mortality rate was 730/100,000 live births in 2001, a decline from the 1990 figure of 1,050/100,000 live births (DoSH, 2001). For women pregnant or in labour, the most important causes of morbidity and mortality are malaria, anaemia, haemorrhage, pre-eclampsia, sepsis, and ectopic pregnancy. The proportion of maternal mortality was highest for women less than 20 years and above 40 years and varies between the various regions of the country. The HIV prevalence rates were only 1.1% for HIV 1 and 0.6% for HIV 2 (DoSH Sentinel Bulletin, 2005).

4.6.1. Antenatal and basic obstetrics care

Antenatal care in The Gambia is part of the Maternal and Child Health (MCH) programme and is part of routine health activities at the primary care level. Antenatal care shares a lot of common resources with other basic health interventions at the health facility level. The clinics are run from base facilities, which range from dispensary to minor and major health centres located in various parts of the country. In order to complement the work of base facilities in MCH including ANC, outreach clinics are held every month in the remote rural villages by MCH teams. The team comprises one State Registered Nurse Midwife (SRNM), one State Enrolled Nurse (SEN) General, one Community Health Nurse Midwife (CHNM), two Community Nurse Attendants (CNAs), one Senior Health Superintendent (SHS) and a driver.

The team uses an ambulance at the base facility to travel to these outreach facilities on a monthly basis. In terms of roles, the SRNM is responsible for ANC and is assisted by the CHNM and one of the CNAs. The SEN and one of the CHNMs are responsible for the Infant Welfare Clinic. Outreach services are necessary because base health facilities are usually located at comparatively high population centres at the expense of the rural communities. Outreach health facilities do not have any resident health staff, but locally recruited Traditional Birth Attendants (TBAs), who are trained in basic health care and operate on a voluntary basis. They are sometimes located in key primary health care villages. TBAs are assisted by government employed CHNs. Due to the decentralisation of the health system, Divisional Health Teams (DHTs) are responsible for monitoring and supervising all basic health facilities and they are also expected to visit each facility, including outreach facilities, at least once every month.

According to results of the Safe Motherhood Needs Assessment of The Gambia (DoSH, 1999), 51.6% of health facilities, including all hospitals and major health centres, provided 24-hour maternity services including at weekends. About 36% of the facilities had a 24-hour on-call service for complicated deliveries, but only 6.25% had on-call services for obstetric surgery. Overall, 45% of health facilities provide basic obstetrics care while only 20% provide caesarean section and blood transfusion. Access to these services is highest in areas where the hospitals are located.

A client flow study conducted for DoSH in 2000 by Frances Foord et al reported that the task-orientated nature of midwives work in antenatal clinics contributed to many women receiving inadequate level of care (DoSH, 2000). ANC is jointly organised with Infant Welfare Clinics in all levels of the health delivery system except for hospitals. Out of the 24 clinics, 23 provided antenatal services alongside infant welfare services. In most of these clinics it was reported that women saw between 2-4 staff members, or up to seven when they registered for the first time. The average total contact time with an individual woman, excluding vaccinations and laboratory tests, was 6.66 minutes and the range time spent at the clinic was 4-261 minutes (DoSH, 2000). Women receiving holistic care had more time with the lead midwife and spent less time in the clinics; 69.7 minutes compared to 119.8 minutes for those receiving fragmented care. Where haemoglobin estimations took place, it took between 24 and 50 minutes at major health centres.

4.6.2. Health care financing

The sources of health expenditure are mainly government, donors and to a limited extent, households. Total government expenditure for health was US$6 million for the recurrent expenditure in 2003, and US$4.86 million for the development budget. Total public expenditure on health as a percentage of GDP was 7.9% in 2003 and 8.1% in 2004 (WHO, 2006) and per capita total health expenditures (average 2003 and 2004 US Dollar exchange rate) was $21 each for 2003 and 2004. In addition, the health sector received a total of US$1.33 million from the Highly-Indebted Poor Countries (HIPC) resources in 2003. General government expenditure on health as a percentage of total health expenditure was 40% in 2003 and 2004 (WHO, 2006).

External resource as a percentage of total health expenditure was 22% (WHO, 2006). The proportion of the public health budget (both recurrent and development) spent at PHC level was 22.3%, with 28.6% at secondary level, 28% at central level including subvention to the tertiary hospitals, 6% on pharmaceuticals and 42% on the development budget (WHO/DoSH, 2005). The rest of the budget was divided between the national laboratories, health training schools and maintenance of the physical infrastructure. The recurrent public health expenditure as a share of the total government expenditure excluding debt servicing ranged from 10.8 -13.4% in 2003. The details of the rest of the financial indicators are in Table 4.2.

Table 4.2 Health Financing Indicators 2003 – 2004

Indicator	2003	2004
GDP	10,026	12,036
THE	809	953
GHE	324	383
GHE % THE	40	40.2
Pvt HE	485	570
PvtHE % THE	*60*	*59.8*
of Pvt HE net out-of-pocket	325	380
Out-of-pocket % THE	*40*	*40*
External funding	176	210
External Funding % THE	*22*	*22*
THE per capita (at exchange rate)	21	21
GHE per capita (at exchange rate)	8	9
THE% GDP	8.1	7.9
PvtHE % THE	60	59.8

Source: Compiled from WHO website and AFRO Health Report (2006)

Cost recovery was introduced in 1988 with the establishment of a drug revolving fund and the introduction of user fees. The Bamako Initiative (BI) was introduced in 1993 as a further development of the cost recovery programme (Bamako Initiative Strategy, DoSH, 1993). As part of the programme, Gambian patients pay D5 ($0.17[4]) for each outpatient visit, registration at the antenatal clinic or a registration of a child at the MCH clinic. Non-Gambians pay between D20 ($0.70) to D50 ($1.74) for the same services. Admission per week in a public ward costs D25 ($0.87) in rural hospitals and D50 ($1.74) in urban hospitals for Gambians and D200 ($6.96) for non-Gambians in 2003. Admission to a private ward of a public hospital cost D750 ($26.10) per week at the RVTH. According to the household income and expenditure survey of 1998, Gambians were willing to pay an average of D35 ($1.22) per private health consultation, D54 ($1.88) per private clinic visit, D168 ($5.85) per private hospital visit and D70 ($2.44) per traditional healer consultation (CSD, 1998).

4.7. THE STUDY LOCATION

The study took place in the two trial sites, Lower River Division (LRD) and North Bank East (NBE) Divisional Health Teams (DHTs) and involved 14 antenatal clinics. The two Health Districts (NBE and LRD) chosen for the trial are on the opposite banks of the River Gambia (see Figure 4.1).

4.7.1 North Bank East

The North Bank is located in the northern part of the River Gambia. It stretches from the Atlantic Ocean in the West and is bordered by Senegal in the North and Central River Division in the East. NBE comprises the three chieftaincy districts of Lower, Central and Upper Badibu. A Chieftaincy District is an area administered by a traditional ruler called a chief. The length of the whole division is estimated to be around 130 kilometres whilst the width varies from 7.5 kilometres to 28 kilometres (DoSH, 2001a). It is divided into two administrative health divisions, with headquarters in Essau (DHT-West) and Farafenni (DHT-East). The Divisional Health Teams supervise health services within each health division. Primary and secondary health services are delivered mainly through PHC posts, and health facilities funded by the government, private organisations and NGOs.

The population of North Bank East (NBE) is estimated at 85,525 according to the provisional results of the 2003 population census as in Table 4.1 (CSD, 2003).

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[4] The USD equivalent was calculated using the average end of year (2003) money exchange rate of D28.7344 to $1.00 The USD equivalent of other amounts are in parenthesis

This represents an increase of 42% over the decade (1983-1993). The annual growth rate is estimated to be around 3.2%, i.e. 1% less than the national figure of 4.2% (CSD, 1993). Among the five provincial divisions in the country, the North Bank as a whole is the second most densely-populated, reaching a level of 68 persons per sq. km (1993 census). Commercial activities are more pronounced in Farafenni in Upper Badibu. The main ethnic groups are Mandinka (49%), Wolof (24%), Fula (20%), Jola (2.8%) and Serer (2.0%). About 14% of the population are non-Gambians, mainly from Senegal, Guinea Conakry, Guinea Bissau, Mauritania, etc. The main economic activities of NBE include subsistence farming, gardening, livestock rearing, fishing, tourism and petty trading.

4.7.2. Lower River Division

The LRD stretches from Burumang Bridge to Pakaliba, with Western Division to the West and the Central River Division to the East. It is bound on both the north and south by one of the regions of Senegal, Cassamance. LRD comprises the six chieftaincy districts of Kiang East, Central and West; and Jarra East, Central and West. It has one administrative health division, with headquarters in Mansakonko. The Divisional Health Teams supervise health services within each health district. Primary and secondary health services are delivered mainly through PHC posts, and health facilities funded by the government, private organisations and NGOs. The population of LRD is estimated at 72,546 according to the provisional results of the 2003 population census as in Table 4.1 (CSD, 2003). The annual growth rate is estimated to be around 1.67% (CSD, 1993). Commercial activities are more pronounced in Soma but a weekly Lumo is held in Bureng and Kwinella. Lumo is a weekly local market where rural people meet to buy and sell goods. The main ethnic groups are Mandinka (70.3%), Wolof (2.5%), Fula (20.9%), Jola (1.3%), Sarahuleh (3%), Serer (0.4%) and the rest represent other minor ethic groups. The main economic activities of LRD include subsistence farming, gardening, livestock rearing, fishing, tourism and petty trading (CSD, 1993).

4.7.3. Appropriateness of study area

The study area is an appropriate representation of a typical rural setting in The Gambia where formal employment for women is almost non-existent. The women in these areas are mainly involved in subsistence farming and household work. The results of the nationwide survey on maternal mortality (DoSH, 2001) revealed that maternal mortality is higher in one of these two regions (LRD), and is second only to CRD in the whole of The Gambia. Furthermore, according to the National Household Poverty Survey Report (CSD, 1998), LRD and CRD are ranked as the poorest regions in the country.

Therefore, conducting such a study in this area can provide information on the underlying factors contributing to low antenatal attendance and high levels of infant and maternal mortality in the area.

North Bank Division hosts the British Medical Research Council's Reproductive Health Research Programme. In this area, people had previously participated in trials, which may have resulted in them being more receptive to researchers, with a resultant positive influence on the response rate and quality of the responses compared to those living in other parts of the country without the same experience. It is perhaps useful to add that an IPTp trial and CEA study in this part of the country is long overdue, because after many trials in the area, this is the only one that incorporates an economic evaluation.

The downside of the choice is that being attached to an ongoing trial means fewer options in terms of choosing the sample outside the trial. In the case of this study, since NBE and LRD were the bases for the IPTp trial, and the economic study was attached to that trial, options to choose other areas were not available. The opportunity to include other areas of the country into the trial would likely make the sample more representative. Furthermore, people being used to research could equally make them less receptive. From the experience of the candidate, certain villages have already started criticising researchers for taking endless samples without giving anything in return. However, it must be clarified that these criticisms are in the minority.

4.8. SUMMARY

The chapter has provided an overview of the study country, The Gambia. The physical (geographical and climatic), demographic profiles and the general economic situation were also described. Poverty and gender situations of the country and their impacts on women were assessed. The health systems of The Gambia in general, and with emphasis on the health delivery system including antenatal and obstetrics care and health care financing, were reviewed. The chapter ended with a detailed description of the IPTp trial settings of North Bank East and Lower River Division and advanced reasons for the choice of those sites. The key message of this chapter is that The Gambia is a poor country with low per capita income and poor health indicators coupled with inadequate health infrastructure.

CHAPTER 5: AIMS, OBJECTIVES, AND DATA COLLECTION METHODS

5.1. INTRODUCTION

This chapter describes the objectives, data collection and analysis methods of the study. Section 5.2 describes the relationship of the cost-effectiveness study to the IPTp trial while Section 5.3 presents the objectives of the IPTp trial. The specific objectives of the empirical part of the thesis are presented in Section 5.4. The conceptual framework used to analyse the costs and consequences is presented in Section 5.5. The challenges of moving from efficacy to effectiveness and how to tackle research and protocol-driven costs are the subject of Sections 5.6 and 5.7 respectively. Section 5.8 closely looked at anaemia and the measurement of haemoglonin (Hb). The approaches and tools used in data collection, including piloting, sampling and data processing are described in Section 5.8. Summary of data collection methods used to estimate IPTp costs, treatment costs of LBW and anaemia are described in Section 5.10. Section 5.11 describes the valuation methods used to estimate indirect costs particularly unpaid household work. Sections 5.12 and 5.13 focus on health consequences and resource savings respectively. The incremental cost-effectiveness ratio (ICER) including sensitivity and data analyses is the subject of 5.14. The chapter ends with a summary in Section 5.15.

5.2. THE RELEVANCE OF THE STUDY TO THE IPTp TRIAL

There is good evidence that IPTp is an effective strategy to decrease the risk of moderate/severe anaemia and low birth weight in primigravidae (IPTp Study Protocol MRC, 2002), but there are no estimates on the impact in multigravidae. A randomised, placebo-controlled trial of intermittent preventive treatment with SP in Gambian multigravidae carried out to test this was a collaborative effort between the Medical Research Council (MRC) Laboratories, the Department of State for Health in The Gambia (DoSH) and the Gates Malaria Partnership at London School of Hygiene and Tropical Medicine (LSHTM). The trial duration was from July 2002 to February 2004 involving 2,688 multigravidae in rural Gambia (i.e. SP 1,346 women and placebo 1,342 women) who received up to four doses of SP during the pregnancy period and were followed up until six week post-partum (Mbaye et al, 2006). The trial and the cost-effectiveness were approved by the Ethical Committees of The Gambia and London School of Hygiene and Tropical Medicine.

5.3. OBJECTIVES AND DESCRIPTION OF IPTp TRIAL

The main objectives of the IPTp trial included establishing the efficacy in multigravidae of SP as IPTp in a randomised-placebo controlled trial and assessing its cost-effectiveness against current treatment.

In the case of primigravidae, the trial aimed to assess the effect of using SP as IPTp in the dry season (January-June) and whether folate supplementation increased the incidence of treatment failure. The specific objectives were to:

(1) Estimate the efficacy of intermittent SP in multigravidae in a randomised placebo-controlled trial on:
    (a) Primary endpoints: prevalence of post-partum anaemia and low birth weight;
    (b) Secondary endpoints: prevalence of placental malaria (sub-sample) and perinatal and neonatal mortality;
(2) Determine whether to apply malaria prevention in pregnancy only during the rainy season;
(3) Determine the cost-effectiveness and acceptability of IPTp and
(4) Determine whether it would be beneficial to delay folate supplementation for two weeks following administration of SP in women receiving IPTp.

From the above objectives, (1) and (3) are concerned with multigravidae while (2) and (4) with primigravidae. Since the focus of this thesis is on multigravidae, the rest of this section shall be restricted to that group of pregnant women. The study sample was originally estimated to be at least 2,688 multigravidae recruited from 14 clinics in the North Bank East health district on the east and west of Farafenni (8), and clinics in and around Soma on the South Bank (6). A fieldworker purposely recruited for the trial was based at each clinic to work with the Maternal and Child Health (MCH) team during the monthly antenatal clinic visits organised in the nearest health facility. In addition, the fieldworker made follow-up home visits to study subjects. In order to be considered for the trial, women had to meet the inclusion and exclusion criteria for the trial. The procedure was that women first went through routine antenatal examination and registration, before being directed to the unit of the clinic identified for the IPTp trial. The inclusion criteria were willingness to participate and to accept to be followed–up, being resident in the trial area and pregnant for at least 16 weeks but less than 32 weeks of gestation at first visit to antenatal clinic. Excluded were those with severe malaria, severe anaemia (Hb <6g/dl), obstetric complications that required admission and history of adverse reaction to sulpha drugs.

5.3.1. Follow-up part of the IPTp trial

The follow-up was not part of routine antenatal care in The Gambia and so all aspects of it were brought about by the trial. After the recruitment of the women, twice weekly home visits were scheduled to see whether they were ill. Those suspected of having severe anaemia at any point during the trial had their blood taken for haemoglobin and parasitaemia and were referred to hospital.

If a woman was ill and needed urgent medical attention, the Community Health Nurse (CHN) within the area was informed. If the CHN was not within reach, the State Registered Nurse Midwife (SRNM) was informed. It was the fieldworker's duty to make sure that a health worker saw the woman on the same day.

If a woman was referred after taking the medication for severe anaemia or clinical malaria, she remained in the study and the SRNM or the Clinical Epidemiologist was informed as soon as possible. If a woman died at home during pregnancy, delivery or six weeks after delivery, the Clinical Epidemiologist or the Principal Investigator was informed immediately. If a baby born alive died in the first six weeks of life, the SRNM was informed, who then scheduled a date for verbal autopsy with the family. The verbal autopsy is attended by both the SRNM and the fieldworker. Clinic staff, at any time during the trial, performed a blood test for haemoglobin estimation on any woman suspected to be severely anaemic. Any woman who developed a clinical attack of malaria during the study was treated with chloroquine and with careful follow-up and treatment with quinine if there was no improvement within 48 hours. At each clinic visit, women were questioned about side-effects or complications of the study medication. Any woman with a possible sulpha drug reaction had her blood taken for haemoglobin and parasitaemia, and did not receive any further doses of SP (MRC, 2002).

5.3.2. Objective of the economic evaluation component of the trial

The economic evaluation component of the IPTp trial aimed to estimate the cost-effectiveness of adding SP as IPTp to routine antenatal care for multigravidae compared with routine antenatal care alone.

5.4. SPECIFIC OBJECTIVES OF THE THESIS

The specific objectives are:

1. To examine the cost-effectiveness of introducing SP as IPTp for malaria into normal antenatal care for multigravidae women in rural Gambia;
2. To explore various methods of valuing indirect costs and to assess the extent to which they affect the cost-effectiveness ratio; and
3. To make policy recommendations on whether or not to introduce SP as IPTp on cost-effectiveness grounds.

5.5. THE CONCEPTUAL FRAMEWORK

The framework for the analysis outlined in Figure 5.1 was adapted from Drummond et al (1995), and also incorporated the new framework of Drummond et al (2005) outlined in Chapter 2. The study is conducted from societal perspective and costs divided into direct and indirect components. Direct costs refer to the resources used in the delivery of health care to patients (preventive and/or treatment). Indirect costs are the output losses due to stoppage or reduction of productivity due to morbidity (Clarke et al, 2000). These losses of output in rural Gambia are associated with unpaid work including subsistence farm work and all aspects of unpaid household work including childcare. This cost categorisation makes it possible to assess the effect of indirect costs on the incremental cost-effectiveness ratio (ICER). Furthermore, those interested in the various cost components could readily re-estimate the result by using the perspective of their choice. Figure 5.1 shows the additional costs and consequences engendered by the introduction of the IPTp intervention over routine antenatal care in The Gambia. In the recent edition of Drummond et al (2005), a new terminology, productivity losses and gains, was introduced. Nonetheless, as indicated in Chapter 1, the concepts in the new framework in Figure 5.1 and the new one in Figure 2.1 are the same. For instance, direct costs and benefits denote resource use (costs) and/or saved (benefits) by the intervention when compared to the alternative. Indirect costs and benefits have been replaced by the term productivity losses and gains. Given the extensive use of the term 'indirect costs' in the literature, this terminology is retained here.

Figure 5.1 Cost-effectiveness of IPTp for multigravidae

Costs	**Consequences**
I. Direct costs to provider (C_1) e.g. • Health sector staff's time • Supplies • Equipment • Power • Overhead costs related to IPTp and treatment **Costs to others sectors (C_2)** **II. Direct costs to patients and their families (C_3)** • User-fees • Travel costs • Out-of-pocket expenses • Patients and family direct inputs into treatment **III. Indirect costs (productivity losses) to patients and their families (C_4)** • Time lost from subsistence farm work • Time cost from household work • Patients and family direct inputs into treatment	**I. Reduction in LBW and anaemia cases and deaths** **$(C_1 + C_2 + C_3 + C_4) - (S_1 + S_2 + S_3 + S_4)$** **II. Resource savings due to reduced treatment (E)** • Savings in use of provider resources due to less treatment • Savings in direct resource use of patients and their families • Savings in unpaid time lost that would have been used in treatment **III. Reduction in DALYs lost (E)**

Adapted from Drummond et al (2005; 1995).

5.5.1. Cost of IPTp intervention

The costs of providing IPTp at the clinic level are those incurred by the provider, patients and their families and the society as a whole. The methodology follows an incremental cost-effectiveness approach of current practice (i.e. ANC), against the intervention which is - IPTp added to routine care with ANC being delivered through existing antenatal clinics.

5.5.1.1 Cost to the provider

The provider of health services is the DoSH through health facilities such as health posts, dispensaries, minor health centres, major health centres and hospitals. The direct cost of the whole intervention to the provider includes health staff time, drugs, medical supplies, consumables, hospitalisation costs, etc. These costs can be categorised as costs incurred during clinic visits for prevention or treatment.

5.5.1.2. Cost to users[5]

The users here refer to multigravidae pregnant women enrolled in the IPTp trial and those treated for malaria during pregnancy. The cost to users is divided into direct and indirect.

Direct costs

In the case of the IPTp intervention in question, direct costs include patients' travel expenses to clinics to obtain IPTp, other out-of-pocket costs such as user-fees as well as costs incurred by family members who sometimes accompany the pregnant woman to antenatal clinic sessions.

Indirect costs

Indirect costs of the IPTp intervention is mainly incurred by women and their caregivers. They are usually in the form of time loss from subsistence farmwork, time loss from household work and family and patient time inputs as indicated in III of the Conceptual Framework (Figure 5.1) and C4 in Figure 2.1. This is mainly because most of the women and their caregivers in rural Gambia are not engaged in any formal employment.

Another area of time use is during the treatment of LBW and anaemia. It is anticipated that those not on IPTp will travel more frequently to hospitals for treatment than those on IPTp since the chances of treating more LBW babies and anaemic mothers are higher than when IPTp is introduced.

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[5] Users are the women who attend antenatal clinics and those who become sick and had to seek treatment at hospital level are known as patients.

Others may use the services of local drug sellers (pharmacies) and traditional healers. In addition to the time incurred by patients and their caregivers, the time input of other relatives in the treatment process is likely to be a high proportion of their subsistence and household work times. Therefore, the time use and indirect costs incurred in each case may be important elements in determining the cost-effectiveness of the intervention.

5.5.2 Consequences of IPTp intervention

The consequences of IPTp are expressed in three forms, which are:

1. Cases of LBW and anaemia averted;
2. Deaths from LBW and anaemia averted and
3. DALYs from LBW and anaemia averted.

5.5.2.1. Reduction in cases of and deaths from LBW and anaemia

The immediate health consequences of IPTp include cases of LBW and anaemia averted due to a lower incidence of malaria in pregnancy. In the same vein, lower incidences of LBW and anaemia could in turn lead to lower deaths from the two conditions than before IPTp. Hence, deaths from LBW and anaemia because of IPTp would be averted.

5.5.2.2. Disability-Adjusted Life Years (DALYs) averted

The outcomes of this study are also expressed in terms of cost per DALYs averted. It is anticipated that the IPTp intervention causes more DALYs to be averted than routine antenatal care without IPTp. DALYs averted by introducing IPTp as part of routine antenatal care in rural Gambia are estimated by calculating DALYs with and without the IPTp intervention. In line with Homedes (2000), Murray (1996), Fox-Rushby, and Hanson (2001), the process incorporates weighting for life expectancy, age, future time and disability. Life expectancy for each age was obtained from the WHO website (WHO, 2003) and the deaths from LBW and anaemia were estimated using case fatality rates from records and previous reports. Disability weights were obtained from the Global Burden of Disease Study (Murray & Lopez, 1996) and the duration of the episodes of anaemia and LBW were collected from both the IPTp trial data and additional data obtained from hospital statistics.

5.5.3. Resource savings to providers, patients and their families

Savings to providers, patients and their families are categorised into savings in direct costs to the provider and savings in both direct and indirect costs to patients and their families.

5.5.3.1. Reduction in direct costs to the provider

This cost component refers to the savings in resource use to the providers resulting from fewer babies and mothers being treated for all types of LBW and anaemia due to the IPTp intervention. These savings include staff time, the use of equipment, drugs, laboratory facilities, beds, overheads and referral costs. Resource savings free some scarce health care resources (direct costs) for other uses.

5.5.3.2. Reduction in direct and indirect costs to patients and their families

On the side of patients, the savings brought about by less treatment due to the IPTp intervention can also be divided into direct and indirect costs.

Direct costs

The saving in direct costs means spending less in treatment costs for all types of LBW and anaemia by patients and their escorts. These include reduced expenditure on transport and other out-of-pocket expenses. The savings also affect other family members who might otherwise spend much of their valuable funds on treatment. In the case of admissions, it could include extra food and costs related to visits by close relatives.

Indirect costs

In addition to the direct costs savings from the IPTp, there is potentailly a high indirect costs as a result of the IPTp intervention. The indirect costs savings from IPTp are likely to arise from the time patients and their families save due to cases of LBW and anaemia averted. These include the travel time from base facilities or their homes, the time spent waiting to see a health professional and the time spent undergoing treatment. These indirect costs are potentially of importance to this study because the majority of women in rural settings are themselves the family 'breadwinners' (see Chapter 2 for details). Therefore, time lost due to treatment may be very valuable to them since it can affect their productivity at both farm and household levels, especially during the rainy season when everybody is busy working on their farms.

The user's contribution to health care in subsistence economies is generally underestimated and opportunity costs are often not considered at all. According to Abel-Smith and Rawal (1992), even cost-free health services have opportunity costs in the form of costs of forgone wages by the patient and time spent on travel, waiting and treatment. It also includes time invested by the caregiver accompanying the patient. Therefore, opportunity costs may be an important determinant of health service utilisation (Details in Chapter 2).

5.6. EFFICACY TO EFFECTIVENESS

An intervention is considered effective if it improves the health outcome in a typical community setting; and efficacious if it results in improved health under ideal conditions (Haddix et al, 2003, Witter, 2000). It is clear from the description of the trial that, like most Randomised Controlled Trials (RCTs), this trial has been conducted under ideal conditions. Activities at the clinic, such as haemoglobin testing, counselling and all the follow-up activities up to six weeks after delivery, are not part of routine antenatal care in the study setting. According to Haddix et al (2003), since efficacy may not directly lead to effectiveness in practice, the generalisability of the result is questionable. Since the aim of the thesis is to assess cost-effectiveness, a randomised-placebo-controlled trial is considered necessary but not sufficient for the task at hand. Moreover, using placebo as the comparator to SP threatens the external validity of the economic evaluation result because placebo is not the most relevant policy question being addressed by the thesis.

Therefore, comparing the intervention group to their placebo counterparts in this case does not lead to a true measure of cost-effectiveness. This opens the way for the selection of a new comparator (Byford & Palmer, 1998). The relevant comparator in the study setting is routine antenatal care (i.e. current practice). To help address this issue, secondary data have been collected outside of the trial from both published and unpublished sources. The availability of this information is explained in Section 5.10. Two sets of analysis are conducted (Base cases I and II). Base case I, according to the trial, refers to the entire multigravidae population enrolled in the IPTp trial and Base case II only considers those multigravidae who do not use bednets. Presenting the results in Base cases I and II was necessary because the trial analysis found that results were different between multigravidae sleeping under a bednet and multigravidae not sleeping under a bednet (Mbaye et al, 2006).

5.7. TRIAL/RESEARCH AND PROTOCOL DRIVEN COSTS

Trial costs refer to expenses incurred in carrying out research rather than the cost of treating a condition. They also include the cost of procedures in the trial that would definitely not be performed in routine practice and are therefore solely required for the purpose of the trial itself (Johnston et al, 1999). These events may arise due to the close monitoring of patients in the trial or because of the necessity to preserve blinding (Drummond and David, 1991). A problem in using cost estimates from a clinical trial in an economic evaluation is the extent to which the costs include resource use associated with the trial per se (Drummond et al 1997). The standard design of trials involves direct interference with the clinical management of patients, which can result in an atypical and ungeneralisable estimate of resource use (Coyle & Lee, 1999).

The additional costs that are incurred because of the trial design are collectively known as research costs. The two main types of research-driven costs identified in the literature are protocol-prescribed costs and protocol-derived costs.

Protocol-prescribed costs arise from the identification of the clinical outcomes, data collection methods or rigid treatment schedules. Clinical trials normally require frequent monitoring of patients through a higher number of tests, follow-ups and health facility visits than in normal practice (Coyle & Lee, 1999). They can also lead to variation in the management of patients. In the IPTp trial, the blinding of treatment, twice weekly follow-ups to the homes of the subjects, and the frequent availability of tests, are a few cases in point. The frequent data collection schedule in trials may also lead to protocol prescribed costs because they may increase resource use for patients, thereby masking the potential resource difference between treatments.

The third type of protocol-prescribed cost is related to the more rigid treatment schedule for patients in trials than would occur in normal practice, thereby removing a degree of autonomy from the patients' own health care provider. In normal practice, response to treatment may mean reduced dosage of medication, but that is not usually the case in a trial setting (Coyle & Lee, 1999).

Protocol-derived costs occur when the design of the trial leads to the identification and treatment of diseases, which may not have happened outside of the trial setting (Coyle & Lee, 1999). This may take place due to increased testing, thereby resulting in more resource use than would occur in normal practice. The two arms of the IPTp trial, SP intervention and the placebo, are similar in terms of costs at the clinic or prevention stage except for the intervention drug, SP. Another similarity between the two arms is evident in health service use related to the intervention for both the provider and patients. The time for waiting and consultation at the clinic, and the time taken for haemoglobin tests, are also similar. The only difference between the arms is the potential difference in utilisation of health services when the effects of malaria set in before and up to six weeks after delivery. It is hypothesised that those on placebo are at higher risk of catching malaria than those on SP, and therefore, the effect of malaria in terms of pregnancy outcome affects them more. This category of women is likely to spend more time at the hospital and out of their usual activities. From the comparison, it is clear that the trial data in its original form may not lead to any difference in cost for both the health provider and the patients as far as the preventive aspect is concerned.

In the case of the IPTp trial, research costs from the perspective of the provider include all costs incurred at the clinic and during follow-up. Other research costs to the provider include hiring a clinical epidemiologist, fieldworkers, a health economist, trial vehicle, the extra office space provided by the MRC, computers, data entry clerks, and motorbikes. For patients, it is the additional time taken to participate in the trial including the time taken to complete the efficacy and clinic exit questionnaires at the clinics and follow-up questionnaires at their homes. The approaches to tackling issues related to the exclusion or inclusion of trial costs are not always straightforward (Johnston et al, 1999). Including trial costs in cost analysis may overstate or understate the time costs (Rittenhouse, 1996). According to Drummond et al (1997), when collecting resource use data, the resource consequences of the research protocol should be minimised and the delivery of care should mirror that of normal practice. In line with this view, only costs, which have occurred for clinical reasons, have been included in this analysis.

5.8 ANAEMIA

Anaemia is a health condition that involves a reduction in the volume of red blood cells (RBC), consequently leading to a decrease in the concentration of haemoglobin in the blood. The reduction in RBC volume results in a reduced ability of the blood to transfer oxygen to the tissues and organs (http://encyclopedia.thefreedictionary.com; www.dcp2.com). A person with anaemia often appears pale, weak and may feel breathless in severe cases. The causes of anaemia amongst others include nutritional deficiency of iron, folate, vitamin B12 etc; haemorrhage, malaria during pregnancy, genetic disorder and chronic illnesses (ORC Macro, 2005; http://encyclopedia.thefreedictionary.com). Early detection and prompt treatment of anaemia among pregnant women could help prevent LBW, severe complications of pregnancy and delivery and even maternal deaths. Anaemia, especially the severe form requires medical attention but those caused by nutritional deficiency can be treated at home once the condition has been diagnosed (ORC Macro, 2005).

Haemoglobin-testing is the main method of anaemia diagnosis. There are several methods of testing haemoglobin (Hb) including HemoCue Hb 201 + system (ORC Macro, 2005; http://encyclopedia.thefreedictionary.com). The system consists of a battery-operated photometer and a disposable microcuvette, coated with a drug reagent that serves as a blood collating device (ORC Macro, 2005; http://encyclopedia.thefreedictionary.com). The test is conducted using a drop of blood taken from the person's fingertip. The level of anaemia can be classified as severe, moderate or mild based on the Hb concentration in the blood and according to criteria developed by the WHO (ORC Macro, 2005; http://encyclopedia.thefreedictionary.com).

Haemoglobin testing and its related costs are not included in the base case analysis, rather as part of sensitivity analysis in Chapter 9. Hb testing in principle is part of the routine antenatal care services in The Gambia. However, in practice, the test is conducted only in fixed health facilities with laboratory facilities. This means women from outreach facilities without such facilities are referred to undergo such tests.

5.9. DATA COLLECTION APPROACHES AND TOOLS

This section is a progression on the conceptual framework presented in Section 5.5. It describes the methods and tools used to collect data and the approaches used to analyse different data. Details of data processing and analysis are also presented in the section 5.9.3. Resource use is usually measured on a patient-specific or a non-patient-specific basis. Those costs measured on a patient-specific basis are said to be stochastic because they vary between patients in terms of frequency and number. On the other hand, events or costs that are non-patient-specific are said to be deterministic because they are the same for each patient (Johnston et al, 1999). The latter is used in this study because events such as a day in hospital may not require measurement directly for each patient, especially in light of the fact that such costs are unlikely to significantly vary between different patients (Clark et al, 1994). In this way, data collection and research expenditure are minimised without disturbing the accuracy of the information generated (Knapp and Beecham, 1993).

Furthermore, given the difficulty involved in identifying costs of specific conditions, all costs expended in treating LBW, anaemia as well as other diseases are taken onboard. This is done in order to avoid leaving out any unexpected resource use that may be causally related to the intervention in question (Johnson and Weinstein, 1997). Similarly, given that LBW and anaemia can cause a broad range of health problems, it is believed that it would be impossible in many cases for either the patient or the health personnel to state that lost productivity was directly related to LBW and/or anaemia. Therefore, patients reported all lost productivity without attempting to make attribution to LBW or anaemia or other conditions. The implication is that this takes on board all illnesses during the trial, and may compensate for any LBW and/or anaemia case not reported during the same period. The data required for this study was collected through questionnaires, diaries, observational methods, review of existing records and secondary data from peer-reviewed studies and unpublished reports.

5.9.1. Piloting

All the data collection tools utilised in this thesis were carefully piloted before use. This accorded the researcher the chance to refine the questions for better understanding by fieldworkers and respondents; and to have an understanding of the time required to administer the tools. The piloting also made it possible to test coding methods. The clinic questionnaire (See Section 5.10.1 and Appendix 2) was piloted on multigravidae recruited into the trial for the first time. The follow-up questionnaire (See Section 5.10.2 and Appendix 3) was then piloted four weeks later on those who returned to the clinic for the subsequent dose of IPTp.

Each day of piloting was followed by a short meeting of the study staff to share their experiences in the administration of the questionnaire including duration of interviews, the difficulties experienced and respondent fatigue. This was done for 12 weeks until the researcher was satisfied with the content of the questionnaires. Completed questionnaires were handed over to the computer staff to test the data entry processes and run preliminary analysis. The problems experienced on the computing side — such as those related to coding — were recognised to further improve the instruments. Clinic and follow-up questionnaires (Appendices 2 and 3 respectively) were accompanied by detailed manuals of procedures (MoP) (for example, Appendix 4) developed to provide hands-on assistance to fieldworkers. The manuals gave a detailed explanation of questions, sometimes with examples to help the fieldworkers correctly solicit answers and minimise errors. The Time use Diary was piloted in Farafenni and the surrounding villages while hospital study tools were piloted at the AFPRC hospital.

5.9.2. Sampling

From the main trial sample of 2,688 women attending antenatal clinics, a sub-sample of 884 respondents was included in the study. The survey was undertaken with a variety of objectives in mind, including obtaining information on travel times and expenditure on treatment. In order to obtain the required sub-sample of the economic study, the candidate made use of Pocock (1983) and also received assistance from one of the statisticians at the statistics unit of LSHTM. Sample size (n) was calculated using the efficacy rate for IPTp with SP for pregnant women in Malawi and Kenya. The respective efficacy rates are 7% with IPTp and 23% without IPTp and the corresponding figures for Malawi are 10% and 23% respectively. The joint efficacy of the two leads to averages of 8.5% and 23% with and without IPTp. The formula produces the sample size of 254 per arm. A pragmatic approach was therefore taken to increase the sample to 884 because samples of 600-900 are common for this type of study. Furthermore, the higher sample will also cater for future dropouts. The details of the sample size calculation for the IPTp trial and the economic component of the study can be found in Appendix 5.

The sample of 884 was distributed proportionately across the 14 health facilities in the trial. In order to have a representative sample in terms of the seasons of the year, as far as possible, the total number per centre was spread equally per season and month for the duration of the trial. Depending on the number of women that presented at each clinic, every second or third woman was randomly selected to take part in the economic trial. In clinics where only one woman was recruited for the main trial, that person was automatically selected. A sample of 662 women was followed-up in their homes. The difference between the clinic study sample of 884 and follow-up sample of 662 was accounted for by early delivery (before four weeks after first recruitment), travel, those who could not be traced and death. The clinic, follow-up, hospital and time use studies had at least 14 fieldworkers recruited mainly from the study locality. Those deployed at the RVTH were recruited within Banjul and the surrounding towns. All the fieldworkers were trained for varying lengths of time depending on the study.

5.9.3. Data processing and analysis

Before handing the completed questionnaires (clinic and follow-up) to the MRC Farafenni computing staff for data entry, each questionnaire was checked for completeness and accuracy as it was submitted by fieldworkers. Those found to contain errors were corrected at the office level in consultation with the fieldworker concerned. Those that could not be corrected at the office level were referred back to the field for verification. All completed questionnaires were coded and entered using EPI-info 6. In order to minimise error, the data were double-entered using two data entry clerks. The data were then verified and initially cleaned by a computing supervisor. The data, partly cleaned by the MRC staff, were handed over to the candidate who completed the cleaning. By using STAT Transfer 6, the data were easily transferred to SPSS 12.01 for further cleaning and analysis. Both SPSS and Microsoft Excel were used run descriptive analysis including, where appropriate, frequency distribution, means and percentages. All other data were entered by the candidate himself using a combination of Excel and SPSS.

5.10 SUMMARY OF DATA COLLECTION METHODS

Cost data required for this thesis was collected in six phases. The first focussed on the incremental costs of the IPTp intervention to the provider, users and their families using health facility cost analysis, secondary data and clinic questionnaires. The second phase was a follow-up study that gathered information on patients and their families' resource use in treating LBW and anaemia, using hospital data collection forms and follow-up questionnaires. The third and fourth studies, which were conducted together, gathered information on provider resource use for treating LBW and anaemia.

The same studies also collected costs incurred by patients to supplement the information collected at the follow-up stage. The fifth study was a Time Use Survey (TUS) used to measure household time use by women in rural Gambia using observation and recall methods, each combined with a diary. As part of this process, the sixth study — an employment survey — was undertaken using a specially designed form (Appendix 6) to collect employment information in the study areas. The first and second studies were completed by the end of the year 2003 and the rest by June 2004. A summary of the studies undertaken is given in Table 5.1.

Table 5.1 Summary of studies undertaken

Study	Aims	Sample size	Data collection tools
Incremental costs of prevention			
Study 1: Incremental cost of introducing IPTp	To estimate the incremental cost of providing IPTp at the clinic level as part of routine antenatal clinic.		
Provider	Additional resource use of IPTp intervention.	884	Clinic questionnaire and hospital observation study
Users and families	Additional direct costs and indirect costs of IPTp intervention.	884	Clinic questionnaire
Cost of treating a LBW baby and an anaemic mother			
Study 2: Follow-up of users and their families	To estimate the treatment cost of LBW and anaemia to patients and their families	662	Follow-up questionnaire
Study 3: Cost of treating a LBW baby at hospital	To estimate the cost of treating LBW at the AFPRCH and RVTH		Patient data collection form
Study 4: Cost of treating an anaemic mother at hospital	To obtain the resource use consequences of treating a LBW baby at the hospital level.	94	Follow-up questionnaire and facility data collection forms
	To obtain the resource use consequences of treating anaemic mother at the hospital level.		
Provider	Resource use consequences of treating a LBW baby and/or anaemic mother at the hospital level.	2 hospitals	Hospital observation study and secondary data
Patients and families	Additional direct and indirect costs for treating a Low Birth Weight baby and/or anaemic mother.	662	Follow-up questionnaire and hospital observation study
Study 5: Time use survey (TUS)	To obtain the average time spent in hours on each of the activities per women per week.	45	Time Use Diary
Study 6: Employment survey	To obtain payment for work performed by rural women and selected male work.	127	A specially designed data collection form

5.10.1 Study One: Incremental costs of IPTp to providers, users and families

The aim of this study was to collect incremental costs of IPTp to the provider, antenatal care users and their families. The clinic questionnaire was used to collect information on cost and resource use of the IPTp intervention. The clinic and follow-up questionnaires were based on a published costing tool; "an annotated cost questionnaire for completion by patients" (Thompson and Wordsworth, 2001). It is important to note that some of these original instruments, adapted for use as clinic and follow-up questionnaires, were originally designed to be self-administered but due to the high illiteracy level in The Gambia this was not possible.

Therefore, under the circumstances, the study relied on the accurate administration of the questionnaires by fieldworkers. A copy of the clinic and follow-up questionnaires and their accompanying Manuals of Procedure are included in Appendices 2, 3 and 4 respectively.

5.10.1.1 Costs to the health care provider

The costing approach used in this study was the ingredients approach (Section 2.2.4) (Green, 2004; Kumaranayake et al, 1998). In this approach, it is important to accurately assess the major cost drivers of the intervention in order to avoid small inaccuracies translating into overvaluing or undervaluing costs (WHO, 2006). An alternative approach is approximation, which concentrates on categories of inputs that do not form major cost-drivers of an intervention and estimate their costs using past expenditures on them. Approximation is likely to yield estimates that are as accurate as applying a more complicated ingredients approach method and requires less data (WHO, 2006). However, the ingredient approach is used in this study to estimate the incremental costs of adding IPTp to routine antenatal care because of a lack of previous IPTp interventions in The Gambia for which past expenditure records could be obtained.

The cost to the provider includes the incremental IPTp cost to the antenatal care providers in terms of additional use of drugs (SP); increased time for consultation and drug-taking; and an additional 0.6 number of visits (from 3.4 for current practice to 4 for the intervention). This is shown in detail in Table 5.2. Some of this information was gathered through clinic questionnaires and the use of secondary data. The introduction of IPTp requires the use of resources in addition to those required for routine ANC but excluding IPTp programme costs which would not be part of any 'real life' IPTp intervention. It is assumed that the costs are uniform across facilities regardless of whether they are base or outreach. Therefore, other costs related to ANC especially at the base clinics, have not been included because they do not have any significant effect on the implementation of IPTp. This is further explored in Chapter 10 (discussion).

The incremental provider costs of IPTp are divided into the time the staff at the facility spent on IPTp, use of capital, materials and supplies as well as the cost of in-service training for existing health staff and supervisors in-charge of the IPTp implementation. Other important additional costs include the outlay for health promotion activities and mass sensitisation at the trial localities. The resources required for ANC as part of the MCH clinics are indicated in column 3 of Table 5.2.

Table 5.2 Anticipated resource use for IPTp in addition to normal antenatal care

COST TO PROVIDERS					
Cost components	**Base case** Current practice (i.e. routine ANC)	**Incremental** Intervention (i.e. adding SP to ANC)	**Measure**	**Unit price**	**Source**
Drugs (SP)	0	Additional drugs	Number of doses	Price per dose	Drug price list WHO/CMS
Consumables (Hb testing)		Additional consumption	Consumption		MRC purchasing
Drug taking (CHN)	0	Additional minutes	Staff time used (minutes)	Wage per minute	CF & Observation study
Consultation & counselling time (SRNM)	0	Additional minutes	Staff time used (minutes)	Wage per minute	CF & Observation study
Overheads	0	Additional minutes	Staff time used (minutes)	Wage per minute	Records
Number of visits	3.4	0.6 visit	Provider cost of additional visit	Cost per visit	Records & Trial
COST TO PATIENTS AND FAMILY CARERS					
Indirect costs					
Drug taking	0	Additional minutes	Minutes	Cost per minute	CF & Observation study
Consultation & counselling time	0	Additional minutes	Minutes	Cost per minute	CF & Observation study
Waiting time	106	Minutes	Minutes	Cost per minute	CF & CQ
Number of visits	3.4	0.6 visit	Patients and family cost of additional visit	Average cost/visit	Records & Trial
CONSEQUENCES					
Treatment OPD visits:					
Anaemia		Fewer visits	Number of visits	Cost per outpatient visit	FQ & CQ
LBW		Fewer visits	Number of visits	Cost per outpatient visit	FQ & CQ
Admissions (Inpatient)					
Anaemia		Fewer days	Length of stay	Cost per hospital day	FQ & CQ
LBW		Fewer days	Length of stay	Cost per hospital day	FQ & CQ

Key: CF = Client Flow, CQ =Clinic Questionnaire, FQ = Follow-up Questionnaire, Obvs = Observation study

The basis of resource use in routine antenatal care includes measurement of fundal height, weighing, urinalysis in base facilities only, measuring of blood pressure, immunisation, palpation, dispensing of iron and folic acid, and other food supplements. Haemoglobin tests are supposed to be performed but like urinalysis, they are only conducted in major and some minor health facilities as the equipment needed is not available at the peripheral level. The performance of the above tasks requires both human and material resources. These include staff time, materials and supplies, the use of existing facilities such as building space, benches, palpation table, equipment, vehicle and driver. Resource requirements are shown in detail in column 1 of Table 5.3.

The duration of IPTp was calculated by observing of women receiving care, combined with the results of the clinic questionnaire completed by the women when they were first recruited into the trial. The clinic questionnaire made no provision for collecting information on the time the health staff took with each woman at the various stages of delivering IPTp at the antenatal clinics. Therefore, observation methods were used to monitor the time spent in delivering IPTp at antenatal clinics. In addition to that, health providers were asked to indicate the time it normally took to deliver IPTp. In the case of haemoglobin tests with a hemocue machine, one of the MRC field station laboratory staff was asked to estimate the time taken for a haemoglobin test using that equipment. Due to excess capacity in most of the antenatal care facilities, the addition of IPTp to normal antenatal care did not lead to any significant additional resource use of capital items such as additional building space, use of extra equipment purposely to cater for the IPTp. The additional forms of resources use under IPTp are summarised in column 4 of Table 5.3.

Table 5.3 Resource use for routine ANC and IPTp intervention

Resources	Unit of measurement	Routine ANC	IPTp
Recurrent			
Personnel: (1 SRNM, 1 SEN General, 1 CHNM, 1 SHS, 2 CNA, Driver)	Hours	Minutes of staff time of those staff directly involved in ANC.	Additional time on IPTp by SRNM, 1 CHNM and 1 CNA
Supervision	Hours	Time for the DHT supervisory team on ANC	Additional 15 minutes.
DoSH supervisory team for IPTp	Hours	None	Quarterly DoSH supervisory visits to health facilities
Laboratory/ANC staff	Hours	Hb and urinalysis	Staff time for Hb test.
Drugs	Tablets consumed	Iron, folic acid and other drugs as necessary	12 SP per woman for IPTp
Materials and supplies	Physical units	Consumables for ANC and shared consumables for other interventions as well	Additional IPTp materials, e.g. roll of cotton wool, spirit, cuvettes, etc.
Equipment (BP machine, timer, obstetrical stethoscope, balance, rural for measuring height)	Minutes of use	Use on ANC	Use of Hemocue machine
Running cost of vehicles	Kilometres	Proportion of kilometres, number of ferry crossings where applicable devoted to ANC	Depreciation of vehicle for the kilometres covered for the quarterly DoSH supervisory visits
Utilities	Quantity consumed in appropriate units	Water, electricity and telephone apportioned to ANC	Only water used for drinking tablets was considered.
Capital costs			
Building	Space occupied	Space used or proportion of time use per health activity including ANC	None
Building operating & maintenance	Spaced occupied	Space	None
Vehicles depreciation			
Health facility vehicle	Kilometres per annum[6]	Health facility vehicle DHT vehicle Kilometres per trip	This activity is carried out even without IPTp and so no values for IPTp
DHT vehicle	Kilometres per annum	Depreciation for supervisory visits	Supervision even without IPTp
DoSH vehicle	Kilometres per annum	None	Cost per kilometre (CPK) and ferry crossing costs for the quarterly supervisory visits only
Health promotion	Number of health promotion activities	Health promotion activity per annum	Health promotion for IPTp only considered
In-service training	Number trained	In-service training per annum	Initial training to improve IPTp staff

[6] 23% of the kilometre per annum cost represents depreciation charges.

As already mentioned, in addition to the primary data, secondary data from other sources were also used. The base case for the duration of time for routine antenatal care came from the client flow study report commissioned by the DoSH and authored by Frances Foord (DoSH, 2000). The report used a time flow and workload study from the Family Care Health Systems Assessment and Planning Manual. It contains information such as the time taken for a haemoglobin test, waiting, consulting etc.

5.10.1.2 Costs to users and their families

The randomly selected sub-sample of 884 users out of the trial sample of 2,688 was asked to complete interviewer-administered clinic questionnaires. This is much higher than the estimated sample size of 254 in Appendix 5 (see Section5.9.2 for reasons) to counter for dropouts. The questionnaire elicited socio-economic information including occupation and educational status. It also collected information on a range of areas such as time spent waiting for treatment and on consultation, including the time patients took to take SP at the clinic. It sought information on the costs of travel, the distance from the woman's home to the clinic, the time taken to reach the facility, the occupation of the woman and anyone accompanying her, and any other expenses incurred for the purpose of visiting the clinic. For those women accompanied to the clinic, all costs incurred by those accompanying them were also taken into account (e.g. transport costs). Women were also asked about their daily work routines in order to give the researcher an idea of the activities they forgo to attend ANC.

5.10.2. Study Two: Follow-up on resource use of users, patients and their families

The reason for the follow-up study was to collect the treatment cost of illnesses during pregnancy and up to six weeks after delivery that related to patients and their families. Information was collected on any health service use including hospital days, major outpatient visits and even treatment from local drug sellers and traditional healers. The cost information ranged from transport costs; opportunity costs of travel and work times; any out-of-pocket expenses; the place they came from (distance); time spent in the various stages of outpatient departments (OPD) as well as the length of stay in the case of admission.

Opportunity cost in this case is the loss of time for attending clinics and seeking treatment (work and/or non-work time) by patients and their relatives. Those admitted were asked about the number of family visitors they had while admitted, where the visitors came from, fares paid, gifts brought as well as other out-of-pocket expenses. As indicated in Chapter 2, Section 2.4, the social capital element in developing countries means family members and friends perform most of the activities together including caring for the sick.

The visitors mentioned here are not just ordinary persons visiting the hospital, rather close family members who leave their daily work to visit and care for their admitted relatives. The resources used for such visits including time have been included because they represent opportunity cost. The fares and gifts brought have alternative uses and the time could be used to undertake other useful activities had they not been involved in the care of their relatives. Reasons for not seeking care were also solicited for those who were ill and yet sought no care. The follow-up questionnaire is attached as Appendix 3.

5.10.3 Studies Three and Four: LBW and Anaemia treatment costs to providers, patients and their families

The objectives of these studies were to obtain both the provider and user resource use consequences of IPTp and the cost incurred by the provider and users for the treatment of LBW babies and anaemic mothers at the hospital level. The figures obtained for the treatment cost per case of LBW and per case of anaemia were multiplied by the frequency and duration of visits for patients within the sample. The studies were conducted at the AFPRCH in Farafenni, North Bank East and RVTH in Banjul where those affected were likely to receive treatment. Given the nature of the conditions being studied (i.e. LBW and severe anaemia); the sufferers were likely to be admitted to hospital because of the difficulty of being managed at home. Furthermore, the lower levels of care, such as health centres, dispensary or village health services, in the Gambia are poorly-equipped to adequately cater for such conditions.

The cost data were collected by using a combination of observation and patient flow analysis techniques at the OPD of AFPRCH and RVTH (Mugford, 1995; Mugford et al, 1998). The patient data collection form used for this purpose is attached as Appendix 7. Patient-flow analysis records the time from when the patient arrives to be seen by different health care workers until he/she leaves the health facility (Johnston et al, 1999). It is useful for those patients likely to be seen by more than one health care worker. The study observed 86 patients from AFPRCH and 27 from RVTH over three weeks as the basis for the patient resource use estimates in order to calculate the cost of treatment for LBW and anaemia. During this period, resource use data were collected on all patients treated for LBW and anaemia at both the outpatient and inpatient departments of the hospitals. However, patients were not followed up beyond their discharge point from hospital as this aspect of resource use was beyond the scope of this study. The implication for this is that informal care provided by unpaid family members or friends at home which are normally paid for in other places are not taken into account.

5.10.3.1 Study Three: Treatment costs to the provider

The treatment costs to the provider at the outpatient department included tests, drugs and personnel time allocated to treatment for a LBW baby and anaemic mother. The time spent on each patient by health personnel at each outpatient unit was recorded for apportionment purposes. Recording this information was the responsibility of the researcher and the fieldworkers. Health workers also facilitated data collection by observing the time taken at each stage of care, drugs taken, tests conducted, etc. Data collection was followed by interviews with officers in-charge of each activity in the various departments of the hospital. The interview focused on time apportionment per patient, inputs used and staff emolument. A Case Report Form (CRF) and a set of WHO mother-baby costing forms (WHO, 1999) were specifically adapted for use in this study. A CRF is often used in a clinical trial to collect resource use (Mauskopf et al, 1999). The information obtained was used to estimate unit costs.

Studies of health facility costings in The Gambia conducted by reputable institutions were used to obtain the average unit cost of resources at the health facility level. These are the Health Mapping Study (1999), Fabricant and Newbrander (1994) and Financial Sustainability of EPI Programmes (DoSH, 2003). The World Bank supported Participatory Health Population and Nutrition Project (PHPNP) through Synergy International, conducted a Health Mapping Study by costing most health facilities in The Gambia. Fabricant and Newbrander was a World Bank study of all the hospitals and selected lower level health facilities (major and minor health centres and dispensaries) in The Gambia. The Financial Sustainability study — as the name implies — assessed the sustainability of EPI programmes in The Gambia. The general information provided was adapted to the needs of the research and saved the researcher from conducting further detailed hospital costings.

AFPRCH is one of the newest hospitals in The Gambia with no record of comprehensive costing studies. Therefore, to fill that gap and for the purpose of this study, a bottom-up costing of that facility was undertaken. Some baseline data for antenatal malaria, LBW, anaemia were also available at the Epidemiology and Statistics Unit (ESU), DoSH. The costing information obtained from the AFPRCH administration was used to help estimate the outpatient and inpatient costs of hospital stay at AFPRCH.

Hospital Costing AFPRCH

The data required for the hospital cost analysis at the AFPRCH were obtained from several sources. Operating and capital cost information was obtained from the Administration and Accounts unit of the hospital.

The study also made use of previous costing studies and reports in the Gambia, such as Picard et al (1992), Aikins et al (1993), Fabricant & Newbrander (1994) and Synergy International (1999). Hospital statistics on the IPD admissions, OPD visits, beds per ward, and average length of stay (ALoS) were obtained from the Medical Records unit of the hospital. A summary of data sources is given in Table 5.4.

Table 5.4 Data sources

Data	Source
Personnel cost (salaries)	AFPRCH Accounts & Administration
Utilisation data	Medical Records unit, AFPRCH
Equipment list	Hospital wards and offices
Average length of stay, AFPRCH	Ward Records (AFPRCH)
Admission cost, ALoS, RVTH	WHO Health Facility Costing 1995
Depreciation of capital for AFPRCH	Synergy International Health Mapping Study (1999)
Foreign Exchange Rate	Central Bank of The Gambia
Consumer Price Index (CPI)	Central Statistics Department, The Gambia
Consumer Price Index for exports (CPy)	National Statistics Office, UK

Source: Hospital study and published reports.

In order to estimate the treatment costs, the data obtained from the hospital administration were supplemented by existing data from reports. For instance, the annual depreciation cost of buildings, equipment and vehicles for the year 2003 were already estimated by the Synergy International report. The difficulty in getting drug utilisation data for AFPRCH was overcome by using per unit OPD and IPD (maternity ward only) drug costs at Bansang in 1995 from WHO/DoSH (1995) and inflating them to their 2003 values. The 2003 costs were then combined with the utilisation data at the AFPRCH to obtain the cost of drugs.

Due to poor inventory management and lack of an equipment list, the equipment at the various wards, department and units of the AFPRCH were physically counted and priced using the 1995 equipment prices available from WHO/DoSH (1995). Since these prices were in Pounds Sterling, they were inflated to their 2003 values by using the United Kingdom (UK) Consumer Price Index for exports. The Sterling values were eventually converted to GMD using the average pound to dalasis exchange rate for the year 2003, obtained from the Central Bank of The Gambia. The total value of equipment at the AFPRCH calculated by Synergy International (1999) was apportioned according to the respective values of the equipment per department/unit. The 2003 replacement value of the building estimated by Synergy International (1999) was apportioned according to the floor area of departments/units.

Capital items were annualised using a 3% discount rate and their useful life (i.e. 25 years for buildings, eight years for vehicles and five years for equipment).

In attempting to derive the unit cost of outpatient and inpatient anaemia care at AFRPCH, and in order to ascertain the overhead costs that should be allocated to the anaemia care, the various hospital departments and units were categorised into clinical, non-clinical and support (common) services. The clinical departments include the outpatient department, Maternal and Child Health (MCH) clinic, dental and physiotherapy clinics, main operating theatre, Medical ward (male and female), leprosy/TB, maternity, paediatrics and surgical wards. The non-clinical departments include radiology, pathology/laboratory and pharmacy. The support services are administration, cleaning, laundry, catering, maintenance and security. The various departments of the hospital with their respective costs are presented in Appendix 8.

The bulk of the staff was already posted to specific sections of the hospital and therefore their costs were allocated directly to those units. Common service staff members were interviewed to establish how they spend their time. Salaries and fringe benefits for the staff were obtained from the payroll provided by the hospital's Accounts unit. Through the observation study and review of reports, it was established that the average time spent with each patient at the outpatient department was 10 minutes. It was assumed that 80% of a doctor's time was devoted to service delivery (i.e. 80% of eight hours) and the remaining 20% on administration (Synergy International, 1999). It was further assumed that assessment of referral cases at the Accident and Emergency (A & E) department was 10% of unit outpatient costs. The step-down method was used to allocate overhead costs to the various clinical departments.

Step-down analysis of hospital overheads

Step-down costing is normally used to estimate the unit cost of treatments at health facility level and is used in settings where such information is not readily available. Previous guidelines in estimating unit costs concentrate on health care programmes (Creese and Parker, 1994; Drummond et al, 1998). However, in reality, costing is different between programme and health facilities because disease-specific interventions do not normally have joint costs due to the vertical nature of their implementation and the delivery of such interventions at health centres may not require complex setup in terms of flows of overhead costs to consider (Conteh and Walker, 2004; Huff-Rousselle, 2001; Shepard et al, 1998). This lack of guidelines gave rise to step-down costing of health facilities.

The process of step-down costing took seven steps. Step one identified service departments to be assigned unit costs. These include for instance wards such as maternity and paediatrics in this case. Step two asked for cost centres to be defined so as to coincide with the administrative structure of the health facility. These cost centres can be defined as direct, intermediate and indirect. Direct cost centres represent the end point of the production line (Kadama, 1990) —. the actual services delivered to clients or beneficiaries. Intermediate cost centres are those that provide diagnosis and departmental support to the final cost centre level. These include pharmacy, radiology and laboratory. It should however be noted that there is no hard and fast rule for the classification but mainly depends on the objective of costing. Indirect or overhead costs centres are the general services centres as administration, transport and maintenance, which are not directly related to patient care. Step three called for the identification of the full cost for each input by listing all individual line items resources and group them. An example is shown in Table 5.5.

Table 5.5 Example of cost centre

Cost centre	GMD
Personnel	7,000
Administration	1,000
Transport	200
Laundry	2,500
Laboratory	200
Other supplies	800
TOTAL	**20,000**

Step four directed costs immediately to cost centres (Shepherd et al, 1998), identify cost drivers (transport) and spread the cost of a nurse across different wards to reflect their varied workload. Step five allocated all overhead costs to final cost centres. The step-down allocation values for most support services took two steps in accordance with Kirigia et al (1998a; 1998b), who apportioned 86% to inpatient wards and 14% to OPD and then further apportioned the inpatient component to wards using floor space. The overhead costs of common services such as administration, security, laundry, kitchen, cleaning and utilities were first ranked and then stepped-down to the various clinical and non-clinical centres starting with the highest. In the case of administration, it was based on the amount of staff time, the size of the wards in terms of the number of beds, floor space, etc. The allocation from each cost centre continued to filter down to the remaining centres until the direct cost of interest remained (Drummond et al, 1998).

Step six computed total and unit costs for each final cost centre using activity or utilisation data to be able to report the results in terms of visits or hospital days and costs (Shepherd, 1998; Hanson and Gilson, 1993). Step seven reported the findings (see Appendix 8 for details). Other methods of allocating overhead costs apart from the step-down method include direct allocation (or multistage method) and reciprocal methods. The direct method ignores the interaction between cost centres and the allocation of reciprocal services and allocates overhead costs such as administration or housekeeping directly to the final cost centres such as wards (Mogyorosy and Smith, 2005). Therefore, a given ward's share of the administration would be equal to the total cost of administration, multiplied by the ward's share of the allocation basis; say, paid hours for staff in the case of laboratories. The reciprocal method uses mathematical methods to model the interaction between cost centres and allocate costs (Mogyorosy and Smith, 2005). The results are more accurate than those obtained using direct or simple step-down allocation (Ellwood, 1996). Other methods that could be used with the reciprocal method include step-down with interaction, or the multiple allocation method which allows full adjustment for interaction of overhead costs. The reason for selecting the step-down method was to estimate the unit cost of outpatient and inpatient hospital services. Unit cost, which is sometimes referred to as average costs (Creese and Parker, 1994) refers to the cost of providing a single good or service.

Costs of inpatient days in health facilities especially, hospitals, are mostly the main drivers of total treatment costs, and their unit cost could affect the outcome (results) of economic evaluation (Oostenbrink et al; 2003). A unit cost can be attached to various levels of health care provision such as meals, laboratory tests (intermediate) or final cost centres such as the cost of providing a health care service; in this case outpatient department (OPD) visit or a bed-day in specific wards (maternity ward or paediatrics ward). All cost data including unit costs provide useful resource requirement information to run a service (Kadama, 1990), help identify costs and cost drivers for management information, assist in budgeting, help in comparative efficiency of health services across settings (Barnum and Kutzin, 1993; Flassa 1998; Adam et al, 2003, WHO-CHOICE, 2003) and provide a guide to the introduction of user fees to ensure funding is available (Conteh and Walker, 2004). However, despite the importance of unit costs, in many countries especially Low and Middle Income countries (LMCs), the availability of unit cost data is limited (Conteh and Walker, 2004; Oostenbrink et al; 2003). Lack of unit cost information in developing country settings include incomplete or no records of resource use to provider services, missing activity data (number of patients and their diagnosis), often sparse or unreliable data and lack of trained staff required to carryout such costing exercises.

In order to fill the gap, unit costs are often based on data from hospitals participating in clinical trials (Oostenbrink et al; 2003). The lack of unit cost data for both inpatient and outpatient care at the AFPRCH led to the use of step-down cost analysis. As stated earlier, AFPRCH is a new hospital with no previous study of this kind.

Hospital Costing: RVTH

Unlike at the AFPRCH, it was extremely difficult to collect provider cost data from the RVTH. In order to overcome this problem, the 1995 WHO Health Analysis for the Health sector was used as the main data source for this costing (WHO, 1995). Secondary data from the WHO Health Facility Costing report (WHO, 1995) and from a study conducted by Fabricant & Newbrander (1994) were adjusted for inflation using consumer price indices for The Gambia for 2003. Costs were standardised to the base year in order to make them comparable to cost and effectiveness data collected in 2003 for the main effectiveness trial (Haddix et al, 2003). This is usually done by using either the Consumer Price Index (CPI) or a relevant sub-index that directly measures movements in the weighted average of prices of goods and services in what is referred to as a fixed 'market basket' of goods and services purchased by households over time (Haddix et al, 2003). In this study, the sub-component index for health care and services obtained from 2003 data was used (CSD, 2003). In order to obtain the cost per inpatient day, the total admission cost per ward was divided by the corresponding average length of stay obtained from the same report.

5.10.3.2 Study Four: Treatment costs to patients and their families

The direct treatment costs of anaemia (moderate, severe and very severe) to patients and their families were assessed by gathering information through the observation study conducted at AFPRCH and through the use of a follow-up questionnaire. These methods are discussed below. In the case of OPD care for anaemia at the AFPRCH, consecutive patients and their escorts were monitored from the very moment they entered the hospital premises until they left at the end of their treatment. In addition to those seeking health services through the OPD, there were a few pregnant women likely to deliver at the hospital itself. In order not to miss them, women admitted to the maternity ward were constantly followed up until delivery time to ascertain whether they or their babies suffered from anaemia or LBW respectively. For each of the above, the full support and participation of the health authorities was obtained. Those admitted were observed daily until discharge.

Anaemic mothers and LBW babies receiving treatment at the outpatient department were identified by the doctor or nurse in-charge. They were then discretely followed and observed by the researcher/fieldworker (after obtaining their consent) through all stages of outpatient care i.e. from the cashier, medical records, consultation, laboratory and pharmacy until those seen at the outpatient department received their drugs at the pharmacy and left the hospital at the end of their treatment.

During the observation period, escorts were also asked to indicate the amount they had paid (i.e. if they travel by vehicle) to travel to the hospital, the duration of their travel and any out-of-pocket expenses incurred during their hospital visit. Patients who visit OPD on their own accord (without referral from health centres) are usually treated and released and it is only in extremely rare cases that such patients are admitted. The majority of those admitted were referred from health centres located within the catchment area of the hospital. A patient data collection form (Appendix 7) was used to collect this data.

Those very severe anaemic patients admitted were observed by fieldworkers deployed (8am-6pm) at the maternity ward to obtain basic information about the patients, their escorts and any family visitors throughout the duration of the patient's hospital stay. Fieldworkers specifically checked for the number of visitors to a patient, noted the places the visitors came from and the amount and type of gifts (cash and/or in-kind) they brought. They also asked about mode of travel, duration of travel and fares paid, if any. Information on bed fees was obtained from the health staff in-charge of the ward. The data from the outpatient and inpatient care services were collected for 21 days.

Those admitted were assumed to be critical cases usually referred from peripheral health facilities to AFPRCH. Those referred to RVTH were also followed-up by a group of fieldworkers stationed at that facility. Referral costs were included because, given the distance between AFPRCH and RVTH, the resource use consequences to the provider and even to patients and their families were likely to be high.

5.10.3.3 Direct outpatient and inpatient treatment costs of anaemia to patients and families at AFPRCH

The direct cost of hospital treatment to patients and their families includes any expenditure by or on behalf of the moderate and severe anaemia cases seen at the OPD and also for the very severe anaemia cases admitted to the maternity ward.

5.10.3.4 Direct treatment cost to patients and families at the RVTH

The direct costs of LBW (VLBW and ELBW) and very severe anaemia treatment to patients and families at the RVTH were assessed using the same methodology as explained in 5.10.3.2-5.10.3.3). The procedure for data collection at the RVTH was the same as was the case of very severe anaemia cases admitted at the AFPRCH.

5.10.3.5. Indirect costs of LBW and anaemia treatment

In an attempt to calculate the indirect costs of treatment for LBW and anaemia at both AFPRCH and RVTH, it was deemed necessary to measure the time required for the patient/mother and their escort to travel to and from hospital and in addition, measure the contact time between health staff and the patient, as well as the waiting time at the hospital before the patient was seen. In the case of admission, the average length of stay for each condition was measured as well as the time spent by family members at the hospital during the admission. Time use for referrals from peripheral health facilities and AFPRCH, and between the two hospitals, was measured for the patient/mother and escort.

The data required to arrive at the indirect costs of treatment for each condition was collected from the hospitals through direct observation (the time used for each), together with the hourly pay rate - see Sections 5.10.4 and 5.11. Data on travel time was collected through a short interview with the patients/mothers and their escorts. For those admitted, information was also collected on the number of visitors they had per day, the gender of the visitors and the duration of each visit plus any cash and material gifts their visitors brought. The family escorts who accompany women to hospital also leave households as well as subsistence work unattended. In an environment where women work for an average of 18 hours per day and the average number of hours spent working, excluding eating, leisure and dressing times, range from 6-15 hours per day (Chapter 2, Section 2.4), stepping in for an ill relative would mean leaving important work undone. Therefore, unpaid work time (farming, income or household work) lost due to treatment for LBW and anaemia has an opportunity cost to escorts as well as mothers because the time could have been spent on potential income-generating (productive), subsistence or household work. 'Escorts' in The Gambia are usually sisters, sisters-in-law, mothers, mothers-in-law, and grandmothers within working age (observation study).

Women in rural Gambia seek treatment from several sources such as health centres, community health nurses (CHNs), village health posts, local pharmacies, traditional healers, local shops and in very serious cases, hospitals. While this might be true for some conditions, the treatment for LBW and/or severe anaemia is mainly sought from hospitals.

In the case of anaemia, less severe cases could be treated at the outpatient departments but very low and extremely LBW babies require hospital admission. However, due to the erratic electricity supply at AFPRCH, coupled with a shortage of the necessary equipment such as incubators, all cases of LBW babies that require treatment are referred to RVTH.

According to the safe motherhood costing manual (WHO, 1999), severe anaemia cases that do not require admission have to make an average of four outpatient visits (WHO, 1999), and results of a search of hospital records in both AFPRCH and RVTH revealed that the average duration of inpatient care for anaemia was seven days. For LBW, the average length of stay according to the data collected from RVTH was 21 days for LBW babies and 28 days for ELBW babies. These are against an average length of stay of 15 days for the paediatrics ward as a whole (LBW and other conditions).

5.10.4 Study Five: Household time use survey

The time use survey measured household time use by women in rural Gambia using observation and recall methods, each combined with a diary for the purposes of estimating the opportunity cost of their time. Given the similarity in household characteristics and the limited financial resources available for the study, a sub-sample of 5% (n = 45) of the antenatal care (ANC) user survey sample was used for the household time use study. The study area was divided into 14 clusters with each being equal to a clinic in the IPTp trial. Ten clusters of nine households were randomly selected from the 14 clusters. By locating the centre of each of the clusters, and by tossing a coin, the first five households with multigravidae in the direction pointed by the 'head' were selected. This was repeated for the nine clusters. This method is in line with the methodology used by Lule & Allwright (2003). However, instead of using a bottle, fieldworkers were comfortable using a coin in its place.

The study was modelled on the time use survey recommended by the United Nations through the United Nations Statistical Division (UNSD). The survey tools contained patient identification and a diary to record the daily activities of the subjects in minutes, classified by major activities including economic activities for the market, non-market activities, domestic and social activities (UNSD, 2003) (see Appendix 9 for the time use diary). The 'Trial International Classification for Time use Activities' (ICATUS), contained in Appendix 10, was adapted and used alongside the diary. The ICATUS was adapted according to activities usually performed in rural Gambian households with a view to making the time use information uniform and compatible across subjects.

Women in rural Gambia tend to be busier during the rainy than the dry season and so using only one of the two periods may overstate or understate the value of the time of women. In order to avoid bias in terms of seasonal variation of work between the two seasons, data were collected for both periods. As stated in Section 4.2, June-October and November-May represent the rainy and dry seasons respectively. The busy period in rural Gambia is synonymous with the rainy season when most of the rural women are busy cultivating their fields.

Data collection during the dry season used the observation method, and seven consecutive days were used to collect information in order to account for the daily variation in activities and the corresponding times to undertake them. The data required for the observation study were collected through three different steps. First, a group of fieldworkers were recruited, trained on the administration of the diary and deployed at the various sites on daily basis for one week in June 2004 to observe the daily pattern of work by the study subjects. The instrument adapted and used for this purpose is the UN international time use study tools used in many developing countries (UNSD, 2003). A whole week was used for data collection in order to minimise bias due to disproportionate time use by day. In order to overcome problems of intrusiveness through long hours of observation, fieldworkers were asked to report to the households at 8 am when the family would have woken up and to leave by 7 pm. This period is the daytime in The Gambia. Second, 45 multigravidae from the study area were interviewed, 18 from LRD and 27 from NBE as to how they spent their day. Third, since the study was conducted in the dry season, in addition to the daily observation, one day of the survey week (Wednesday) was chosen for all fieldworkers to ask women to recall how they spent their time during the rainy season.

During the recall session, memory-aid techniques were used to assist with the recall for the rainy season. Since the rainy season had already elapsed at the time of the survey (early June 2004), women were asked to recall how they used their time during the period. As a way of jogging their memories, they were asked to state how they spent their time during the rainy season using a list that comprised common activities performed by rural women during the rainy season. The common household work in rural areas was reported by women at the ANC clinics using the clinic questionnaire is shown in Table 5.6. This gives the researcher an idea of the activities women forgo to attend the antenatal clinic. The recall period is not far off from some of the recommended periods for recall to be effective before memory evaporates [(2-3 months, Brown & Adams (1992); 3 months, Rivicki et al (1994)); and 4 months Weissman et al (1996)].

Table 5.6 Key activities performed by women in the study households

Activities
Activities to be performed
Farm work
Gardening
Cooking
Cleaning household
Cleaning utensils
Washing and mending clothes
Shopping
Care of children
Accompanying children to places
Care of the sick and elderly
Supervising children
Care of guests

Source: Clinic Questionnaire.

As already indicated in Section 5.10.4, time use information was also collected for IPTp, outpatient, and inpatient treatment of LBW and anaemia at AFPRCH and RVTH, and referrals between all health facilities. All activities were coded and classified according to the UN classification system. The original UN ICATUS is a one-size-fits-all tool adapted for use in different parts of the world. This common classification is useful to ensure comparability between time use studies within a country, across countries, and to ensure correspondence with existing standard classification in labour and economic statistics and the integration of the time use studies within the field of social and economic statistics (Bittman, 2000). The categories and definitions of the activities in the ICATUS took into consideration the different cultural and geographical context in which the activities are generally carried out, thereby providing a basis for international comparison of time use studies (Bediako & Vanek, 1999). The ICATUS activities are divided into 10 categories according to the way they are treated in the System of National Accounts (SNA). These are:

1. Employment for establishments;
2. Primary production activities (not for establishments);
3. Services for income and other production of goods (not for establishments);
4. Household maintenance, management and shopping for own household;
5. Care for children, the sick, elderly and disabled for own household;
6. Community services and help to other households;
7. Learning;
8. Social and cultural activities;
9. Mass media use; and
10. Personal care and self-maintenance.

These categories were further grouped into three broad categories. 1-3 fall within the SNA production boundary and are usually included in GDP calculations; 4-6 are 'work activities' but fall outside the SNA production boundary comprising mainly unpaid work; and the last group, 7-10 are usually referred to as 'non-productive' activities. The easy method of distinguishing between productive and non-productive activities is to invoke the third party criterion by assessing whether an activity can be performed by a third party on behalf of someone without the person performing it getting the benefit/enjoyment (Reid, 1934). Those activities that can be performed without the person doing the work taking the benefits/enjoyment are productive activities and the converse is true. For instance, household work is productive while eating is not.

5.10.4.1 Reasons for choosing the Observation and Recall methods

Several reasons made the use of the observation method of data collection appropriate. Resources, which are a common problem in such studies, were available to undertake the observation study. Furthermore, given the researcher's interest in the interaction between the women and the fact that these women do not have the literacy skills to complete a detailed written account, direct observation method became the feasible option. Otherwise, one would be obliged to conduct a detailed interview with each woman and then reconcile variations in memories. A clearer overview is obtained from observing them as timing is important for the survey, and the study population does not place the same importance on the measurement of time. The interest of the study is on a relatively small population that can be thoroughly observed, and on which a larger range of context details can be recorded from observation than one can collect from a fixed detailed instrument completed by the respondents.

For a fixed instrument to work, one needs not only a clear conceptualisation of the context information being collected, but also to convey that context information in a way that will be clearly understood and reported by all respondents in a largely similar way. Given that some of the conceptualisations sought are outside their normal range of experiences, this information is more efficiently collected by observation. It was difficult to get fieldworkers in and out during the rainy season, and therefore, for this period it was necessary to resort to the use of the recall method of measuring unpaid work.

5.10.4.2 Study Six: Employment Survey

The aim of this survey was to collect wage information with a view to using it to value indirect costs of unpaid work. The reason for this survey is that unlike many countries where time use studies have been carried out, The Gambia has no labour force survey, and does not conduct one on a regular basis. The entire fieldwork for this part of the study was conducted by full time fieldworkers who were trained and deployed at the study area for a period of 2-3 months. Women and men doing various types of work were asked about their pay and the time of work in terms of hours, days and months in a year. The data were collected through a survey of paid workers in the study site. These included maids, restaurant workers, and market cleaners. A random sample of restaurants (n=15), households with maids (n=15), farm workers (n=15), garden workers (n=15), market traders (n=20), taxi drivers (n=16), shepherds (n=6), water sellers (n=15) and firewood sellers (n=10) were interviewed. Where possible, equal numbers were chosen from each of the Health Divisions (LRD and NBE). The information obtained from the survey was supplemented with secondary data collected from some institutions that employed uneducated women and men within the study area.

These included employment and pay records from AFPRCH in Farafenni, Soma Health Centre, and Department of State for Education (DoSE) School Feeding Programme. The Child Welfare section of the Christian Children's Fund (CCF) was also contacted for information on the payment and in-kind benefits to uneducated mothers employed in their various Day Care Centres.

5.11. VALUATION OF UNPAID WORK

A method was required to value time use. This was done by assigning hourly wage rates to the time use data collected. The wages used were taken from the employment survey conducted in the study area (Section 5.10.4.2). The two methods of valuing unpaid work are input and output methods, as stated in the literature review (Chapter 2). For this study, however, only the input-based approach is used despite the clear advantages of output method (Chapter 2). This is mainly due to a lack of adequate data to use the output method. Furthermore, since labour is one of the biggest inputs in seeking care, it will be necessary to use input rather than output method. However, due to lack of requisite data in The Gambia, a strict use of input method may not be possible. Instead, labour is used as a rough estimation of the value-added by household production. The time measured from the time use survey is converted into monetary units. Labour only estimates are a good start because household production is more labour intensive than production in most other economic sectors.

The choice also made it possible to compare the results with other studies in the same setting that used different approaches (Picard et al, 1992; Aikins et al, 1998) and to test the sensitivity of findings to the selection method.

However, Brathaug (1990) and Budlender and Brathaug (2002) pointed out the possibility for the calculation to underestimate the full value of household production. To estimate the value of household work, the calculated hourly wage rates were multiplied by the time spent on unpaid household work. The four different methods used to value unpaid work are, the opportunity cost approach, replacement cost approach, human capital approach and the frictional cost approach. The opportunity cost approach was used as the base case while the rest of the methods were reserved for sensitivity analysis.

5.11.1 Method One: Opportunity cost approach

The opportunity cost approach, which is the most common costing approach used in The Gambia (Picard et al, 1992 & Aikins et al 1998), was employed in three different ways. First, by using an average wage rate paid to females; second, by using the average wage rate paid to males; and third, by using the overall average wage rate of females and males.

5.11.2 Method Two: Replacement cost approach

The replacement cost method used the wage of a 'generalist', such as a full time paid household worker, as a proxy for the lost unpaid household work. This is the average wage of maids working on a full time basis for civil servants and in private homes in the study setting. The same calculation was repeated for a 'specialist' by multiplying the time for each of the sub-components of household work by their respective wage rates. For this, the wages of those responsible for cooking and childcare at Christian Children's Fund (CCF) day-care centres and primary school cooks in the rural area were used.

5.11.3 Method Three: Human capital approach

The human capital approach (HCA) typically attributes economic value to unpaid household work, but mainly due to methodological or other difficulties involved in its measurement, it sometimes attaches zero values. In this case, only the subsistence component of the work forgone was valued, for the duration of impairment until the person is replaced. This can go beyond the maximum three months period stipulated in the case of the frictional cost approach (see below).

5.11.4 Method Four: Frictional cost approach

The fourth method is the frictional cost approach (FCA) that attributes a zero economic value to unpaid work up to the time the person can be replaced, but only for a maximum period of three months.

Therefore, a zero value was attached to the unpaid household component of the time spent attending the health/clinic facilities for IPTp and/or any subsequent treatments due to LBW and/or anaemia.

5.12. HEALTH CONSEQUENCES

The consequences of interest in this research are the cases and deaths from LBW and anaemia averted using the effectiveness information from the 2,688 women enrolled in the IPTp trial. Information on these health outcomes was analysed and made available by February 2005. The difference in the efficacy values was obtained when the trial blinding was finally broken. Consequences were also expressed in terms of DALYs averted by the researcher. The main trial did not make provision for the collection of information on case fatality rates of LBW babies and anaemic mothers. In order to fill this gap, case fatality estimates for LBW babies were obtained from the literature and those for anaemia came from the Preliminary Indicators (DoSH, 2001) compiled by the DoSH, Epidemiology and Statistics Unit (ESU). Expert opinion was also sought from Dr David Osrin (Institute of Child Health, London) to shed more light on case fatality of VLBW and ELBW babies.

The data on health care utilisation by LBW babies and anaemic mothers in The Gambia was obtained from The Gambia Public Expenditure Review report (DoSH, 2001a) and the WHO Safe Motherhood Costing Manual (WHO, 1999). Table 5.7 summaries the main health outcome measures used in the thesis.

Table 5.7 Outcome measures

	Measures	Sources
A.		
LBW (VLBW & ELBW)	Cases averted	Main effectiveness trial
	Deaths averted	Expert opinion on survival rate (Dr. David Osrin, Institute of Child Health)
	DALYs averted	Estimated
Anaemia (Moderate & Severe)	Cases averted	Main effectiveness trial
	Deaths averted	Preliminary Indicators (2001)
	DALYs averted	Estimated
B. Other outcome data		
	Multigravidae population in NBE & LRD (55,678)	Preliminary Indicators (2001)
	Proportion of non-bednet user multigravidae (22%)	Main effectiveness trial
	Effectiveness data	Main effectiveness trial
	Case fatality rate	Preliminary Indicators (2001)
	Health care utilisation	Safe Motherhood Costing Manual & Gambia Health Policy (2000)
	Expert Opinion on survival rate of VLBW and ELBW	Dr. David Osrin, Institute of Child Health

Source: Main effectiveness trial and reports.

The outcome measures used in this study — cases of LBW/anaemia averted, deaths from LBW/anaemia averted and DALYs averted from LBW/anaemia — were compiled in three different ways. First, the cases of LBW and/or anaemia averted were obtained by multiplying the prevalence rates of each of these conditions by their respective sample sizes and then subtracting the cases for IPTp (SP) from those for routine antenatal care (placebo). Second, in the case of deaths averted, the number of patients who already had the condition was multiplied by the respective case fatality rates to obtain the expected deaths for ANC and IPTp. Third, the differences in number of deaths for ANC and IPTp gave the number of deaths averted because of IPTp. Case fatality rates of 12.5% and 100% were used for VLBW and ELBW respectively, and those used for very severe anaemia cases were 11.8% at AFPRCH and 2.5% at RVTH. The 11.8% represents the LRD regional rate of anaemia case fatality and the 2.5% is the national case fatality rate for anaemia (DoSH[7], 2001). The cases and deaths averted are based on the cases seen at the hospital level.

In line with current practice in The Gambia, all cases of VLBW and ELBW are referred to RVTH via AFPRCH for further care. According to the Safe Motherhood Costing Manual (WHO, 1999), 75% of all severe anaemia cases are 'very severe', while the rest are classified as 'severe'. Further, according to the Safe Motherhood manual (WHO, 1999) and the Standard Treatment Guidelines (STG) for The Gambia (DoSH, 2001), all mild anaemia and 30% of moderate cases are treated at the ANC level with adequate supply of folic acid. The remaining 70% of moderate cases are referred to major health centres, where 90% are treated and the remaining 10% are referred to hospital, in this case the AFPRCH outpatient department.

The majority of the severe anaemia cases (70%) are treated at the major health centre level, while the remaining 30% are referred to hospital. All very severe anaemia cases are referred to hospital for admission through the usual referral channel by using the health centre ambulances. Of those referred from health centres, 95% are admitted at the AFPRCH while the remaining 5% are referred to the RVTH for further treatment. The final outcome measure is presented in the form of DALYs averted for LBW and anaemia. DALYs comprise two sub-outcomes — as Years of Life Lost (YLL) and Years Lived with Disability (YLD) — estimated separately. Both are estimated for routine ANC and then re-estimated after the introduction of the IPTp intervention by using the standard formula and assumptions provided by Murray (1994). The difference between the sum of YLL and YLD before and after IPTp gives DALYs averted.

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[7] Preliminary Health Indicators, The Gambia.

DALYs averted due to the introduction of IPTp for LBW was the sum of DALYs averted for VLBW and ELBW. For anaemia, it was the sum of DALYs averted for those moderate, severe and very severe anaemia cases seen at the AFPRCH and/or RVTH. The age used to estimate DALYs averted for anaemia was the mean age of the women enrolled in the main effectiveness trial (28 years). The details of the assumptions used in estimating DALYs are indicated in Table 5.8.

Table 5.8 DALY assumptions

	Unit	Source
Low Birth Weight		
Age at onset of LBW		
VLBW	1 day	
ELBW	1 day	
Age at death		
VLBW	7 days	Hospital records
ELBW	5 days	Hospital records
Case Fatality Rate (CFR)		
VLBW	12.5%	DoSH
ELBW	100%	Expert opinion (Dr. Osrin)
Period lived with disability		
VLBW	5 years	Literature
ELBW	5 years	Literature
Proportion of girls to boys	50%	Central Statistic Department
Anaemia		
Age at onset of anaemia		
Moderate/severe anaemia	30 years	Clinic Questionnaire
Very severe anaemia	30 years	Clinic Questionnaire
Age at death		Clinic Questionnaire
Moderate/severe anaemia	30 years	Clinic Questionnaire
Very severe anaemia	30 years	Clinic Questionnaire
Case Fatality Rate (CFR)		
Moderate/severe anaemia	0%	Preliminary indicators, 2001
Very severe anaemia	11.8%	Preliminary indicators, 2001
Period lived with disability		
Moderate/severe anaemia	4 days	Assumption
Very severe anaemia	30.4 days	Assumption

Source: Literature, Clinic questionnaire and hospital records.

As indicated in Table 5.8, onset of all types of LBW is day one of birth and those who die from the condition are assumed to die after seven days for VLBW and five days for ELBW. The proportion of those who die (CFR) was 12.5% for VLBW and 100% for ELBW. Those who survive the condition live with the effects up to five years and thereafter live a normal life. Those likely to die from severe anaemia will die at the same age as the age of onset of the condition, which was assumed to be the average age of women enrolled in the trial. Only very severe anaemia cases were expected to die which means the CFR for moderate/severe anaemia is zero.

5.13 RESOURCE SAVINGS

The data required to estimate the treatment cost savings to the provider for both conditions (LBW and anaemia) are stated in Section 5.10. where outpatient, inpatient and referral costs have been estimated. These were combined with the outcome data estimated in Section 5.12 to estimate treatment cost savings to the provider, patients and their families. To estimate treatment cost savings to patients and their families, the direct and indirect costs generated from the previous sections were used.

The cost of treating all cases (non-fatal and fatal) of LBW/anaemia were estimated for each arm of the trial using the costs estimated from Section 5.10. Resource savings are the difference between those treated for the control (ANC) and the IPTp intervention arms. For an effective intervention, cases and deaths from control are expected to be higher than those after the intervention. It is this difference in resource use that is equivalent to savings in treatment costs. These changes in resource use affect all those involved in the treatment and care such as the health care provider, patients, and their families. Resource use savings are estimated for LBW and anaemia for Base cases I and II; and the sum of the savings for the provider, patients and their families represent savings in each case. Where the intervention led to negative cases averted, instead of saving resources, the intervention could lead to depletion of resources by treating more cases of LBW and anaemia after IPTp than before.

5.14. INCREMENTAL COSTS AND CONSEQUENCES

Incremental costs and consequences were estimated for each condition as well as the cost per DALY averted for LBW and anaemia. The incremental costs and consequences were expressed for Base cases I & II. In addition to providing information on the incremental costs and consequences of the IPTp intervention, policy makers also require information on the type of variables likely to influence costs and consequences and the degree of influence. Therefore, sensitivity analysis was conducted by varying several parameters with emphasis on those that affect indirect costs. The parameters included various wage rates, discount rates, number of visits, effectiveness and case fatality rates, and DALY parameters. The effect of each of these on costs, consequences and incremental cost-effectiveness ratios was assessed.

5.15. SUMMARY

This chapter has outlined the study objectives and highlighted the relationship between the study and the IPTp trial. The data collection methods and the studies required to collect the data were set out. Study one used a clinic questionnaire to obtain data to assess the incremental cost of introducing SP as part of routine antenatal care. Study two used a follow-up questionnaire to assess the consequences of LBW and anaemia to patients and their families. Studies three and four obtained the costs of treating a LBW baby and an anaemic mother in AFPRCH in Farafenni and of referral cases from peripheral health facilities to AFPRCH and to RVTH in Banjul. Where necessary, data were supplemented by unpublished sources such as reports and previous studies in the same setting. Study five used time use survey methods to assess how women in a typical rural household in The Gambia used their time to perform various tasks. Study six used a specially designed employment survey form to collect information on employment and payment for a random sample of uneducated women and men in the study area. All six studies provided the requisite data for the cost-effectiveness analysis. Sensitivity analysis was conducted to assess the effects of key variables, especially those affecting indirect costs.

CHAPTER 6: RESULTS I: HOUSEHOLD CHARACTERISTICS AND COSTS OF IPTp AND RELATED TREATMENT.

6.1. INTRODUCTION

This chapter presents the characteristics of the study subjects and their households as well as the costs of IPTp and related treatments in terms of IPTp intervention costs to health care providers and direct costs of IPTp to patients and their families. The focus is on those costs incurred in addition to the cost of routine antenatal care. The chapter is divided into eight sections. The first section contains the introduction, followed by the background characteristics of the study subjects including their demographic profiles in Section 6.2. The incremental cost of the IPTp intervention to the health provider is presented in Section 6.3, while Section 6.4 presents the direct costs of IPTp to patients and their families. Sections 6.5 and 6.6 calculate the incremental cost of IPTp and treatment costs for LBW and anaemia respectively, in order to use these later in the analysis of resource savings. The chapter ends with brief summaries of the results in Section 6.7.

6.2. BACKGROUND CHARACTERISTICS

This section looks at the background characteristics of the sample of 884 women recruited into the trial at the antenatal clinic level as well as the 662 who were later followed-up in their homes. Both household and individual level characteristics were examined. The background information of the sample was generated using a clinic questionnaire (see Section 5.10.1-5.10.1.1, Chapter 5). The characteristics of the women include age, number of living children, ethnicity, educational status, types of marriage. These characteristics were chosen on the basis that they are known to positively or negatively influence the use of antenatal services (Thaddeus and Maine, 1994; McCaw-Binns et al, 1995) and therefore by extension, the use of IPTp in The Gambia. The characteristics of the household heads include sex and education. The details of sample selection are presented in Chapter 5, Section 5.9.2 (methodology).

6.2.1. Demographic and other profiles

Of the 884 women recruited at the antenatal clinics, the ages ranged from 15 to 40 with a mean age of 26.8. Among those whose ages were reported (882), 61 had their ages estimated by the fieldworkers because their ages had not initially been indicated on their antenatal cards. Of the 881 women who stated their ethnic background, more than half (56%) were Mandinka, followed by Fula, then Wolof, with the rest from other smaller tribes. In terms of education, most had Madrassa teaching (81%).

Madrassa, which is Islamic education, is a very common form of education in rural Gambia. Primary and secondary education constituted 6% and 4% of the 884 women. Approximately half of the women were married in monogamous relationships while the other half were polygamous. In terms of occupation, the results revealed that rural women tended to have more than one occupation. Of the 882 women who indicated their occupations, nearly all (99.8%) reported household work as their primary work and the bulk of these were also engaged in farming (64%). The rest also doubled as traders, school cooks, seamstresses etc. Details of the demographic profile are given in Table 6.1. The demographic profile of women in this study is representative of The Gambia as a whole. For instance, Mandinkas form the majority in the country followed by Wolofs and then Fulas and the age brackets of the women recruited for this study are also identical to the age distribution of the female population in the country (CSD, 2006).

Table 6.1 Demographic profile of the study sample

	Frequency	Percentage
SAMPLE SIZE	**884**	**100.0**
Age (years)		
15-19	48	5.4
20-29	542	61.3
30-39	275	31.1
40-59	17	1.9
Ethnic Group		
Mandinka	496	56.1
Fula	237	26.8
Wolof	79	8.9
Other	69	7.8
Education		
No Education	68	7.7
Madrassa	718	81.2
Primary	56	6.3
Secondary	36	4.1
Tertiary	3	0.3
Non-Formal	1	0.1
Don't know	2	0.2
Marital status		
Single	7	0.8
Monogamous	442	50.0
Polygamous	433	49.0
Widow/divorced	2	0.2

Source: Compiled from Clinic & Main effectiveness questionnaires

Table 6.2 shows that the majority (66%) of women recruited in the economic study came from the Lower River Division and 68% of them were recruited during the dry season. In terms of type of facilities, approximately one-third of the women were recruited at outreach clinics (36%), followed by dispensaries (17%).

Table 6.2 Characteristics of the women and the number recruited in the economic study per facility

	Frequency	Percentage
HEALTH DIVISION		
Lower River Division (LRD)	**586**	**66.3**
North Bank East (NBE)	**298**	**33.7**
Clinic		
Farafenni	103	11.7
Iliassa	44	5.0
Kerewan	43	4.9
Ngeyen Sanjal	19	2.1
Njaba Kunda	38	4.3
No Kunda	34	3.8
Pallen Wolof	4	0.5
Sara Kunda	13	1.5
Bureng & WellingaraBa	131	14.8
DongoroBa	30	3.4
Jalambereh	115	13.0
Sare Musa	81	9.2
Soma	229	25.9
Recruitment Season		
Rainy (July - Dec)	279	31.6
Dry (Jan – June)	605	68.4
Type of facility		
Outreach Facility	321	36.3
Dispensary	150	17.0
MCH clinic	103	11.7
Minor Health Centre	43	4.9
Major Health Centre	229	25.9
NGO Clinic	38	4.3

Source: Compiled from Clinic & Main effectiveness questionnaires

The measurement of fundal height or gestational age in the context of this study serves two purposes. Firstly, it indicates the duration of pregnancy at any given point in time. Secondly, it indicates the time at which women report to the antenatal clinic for the first time. According to the trial protocol, one of the main criteria for recruitment was for the women to be at a gestational age of at least 16 weeks of pregnancy. The gestational age of the women in the sub-sample of 884 women ranged from 16-40 weeks.

Table 6.3 shows that the bulk of the women recruited into the trial at 26-30 weeks (43%) were aged 20-29 years. The parities of the women ranged from 2-13 with almost half of them falling within the range of 2-4. The number of living children of the women ranged from 0-9 with 61% having 1-3 children living. Approximately 4% had no children.

Table 6.3 Characteristics of the women and the number recruited per facility

	Frequency	Percentage
Sample size	**884**	**100.0**
Gestational age (weeks)		
16-20	85	9.6
21-25	191	21.6
26-30	381	43.1
31-35	170	19.2
36-40	57	6.4
Parity		
2 – 4	436	49.3
5 – 7	322	36.4
8 – 10	110	12.4
11 – 13	16	1.8
Children alive		
0	33	3.7
1 – 3	541	61.2
4 – 6	276	31.2
7 – 9	32	3.6

Source: Compiled from clinic and main effectiveness questionnaires.

6.2.2. Characteristics of household heads

Of the original 884 women who participated in the trial, 662 (75%) were followed-up in their houses, whilst the rest were lost along the way in the first month of recruitment due to delivery, transfer and travel. Of those followed-up, Table 6.4 shows that the majority lived in male-headed households. The number of wives in these households ranged from 1-4 with most having three or four wives. For the educational levels of the household heads, Madrassa education dominated (74%). The majority of the household heads (71%) stated farming as their main occupation.

Table 6.4 Household level characteristics of the study sample

	Frequency	Percentage
Sample size	**662**	**100.0**
Gender of household head		
Male	653	98.6
Female	9	1.4
Education		
No Education	84	12.7
Madrassa	490	74.0
Primary	18	2.7
Secondary	51	7.7
Tertiary	4	0.6
Non-Formal	13	2.0

Source: Compiled from follow-up questionnaire.

6.2.3. Summary

It has been shown in this section that the ages of the multigravidae recruited for the trial ranged from 15-40, with the mean age being 26.8. Half of the women are Mandinka, the largest ethic group in The Gambia and most of them and their husbands had Madrassa education.

6.3. INCREMENTAL IPTp IMPLEMENTATION COSTS TO THE PROVIDER

The costs of the IPTp intervention can be generally divided into recurrent and capital costs, borne by the health provider and by patients and their families, as well as those borne externally to the wider health sector (Drummond et al, 1997). The costs of the IPTp intervention to the provider are presented in terms of total provider costs per health facility and average cost per patient per facility, and also incremental costs by inputs. Costs are presented in terms of Base cases I and II (see Section 6.3.1. for details on Base cases I and II).

6.3.1. Total provider cost of IPTp by health facility

The subject of interest in this study is multigravidae, who form a major component (75%) of those women who attend antenatal clinics in The Gambia (from facility records of antenatal attendance and the records of women who deliver at health facilities, the proportion of multigravidae to primigravidae was 3:1). In order to obtain the total cost per facility, the unit cost per facility was multiplied by the number of multigravidae for that health facility. The sum of the sub-totals for the two divisions gives the total for the study site.

Two different samples were used for this study to obtain total costs. The sample size in the first case (Base case I) is the main trial data extrapolated to the total multigravidae population in the trial site and the second (Base case II) is the extrapolation of those multigravidae who do not sleep under bednets. In order to obtain the sample of multigravidae, the population of women within childbearing age of 15-49 years in the two study districts was projected, using the 1993-2003 average annual national population growth rate of 4.2%, and population figures of 68,373 in year 2001 and 74,236 in 2003 and their corresponding antenatal care utilisation figure in LRD and NBE. Taking 75% of this figure, which represents the proportion of multigravidae among women of childbearing age, gave 55,678 (34, 980 for NBE and 20,698 for LRD). This represents the number of multigravidae in NBE and LRD regardless of whether they took part in the trial or not, because any future change in policy would affect every multigravidae and not only those who took part in the trial. To obtain a sub-sample of non-bednet user multigravidae in the study site, 22% of 55,678 was taken, to give 12,249. The 22% represents the proportion of those multigravidae not sleeping under bednets as reported in this trial.

From Chapter 5, Section 5.10.1.1, the two methods of observation and health provider estimates, plus use of secondary data, gave an approximate total time of six minutes for the three health staff involved in IPTp, with a mean time of two minutes per woman per staff member. This included the time for counselling of women about any likely side effects of taking drugs, time consumed in taking SP at the clinic, and all other potential time resource use activities associated with IPTp. For the remaining three visits to the health facilities for IPTp, it was assumed that half the time taken per woman (three minutes) in the first visit was needed per additional visit. This estimate of time for subsequent visits is consistent with the six minutes reported by Goodman et al (2001) in their cost-effectiveness analysis of antenatal malaria prevention in Sub-Saharan Africa.

6.3.2 Results: Base case I - Recurrent and capital costs

By multiplying the estimated unit cost per facility and the projected clinic utilisation figures, the total incremental recurrent cost incurred by 34,980 women in NBE was D525,845 and the amount for the LRD incurred by 20,698 women was D311,470. This is shown in Table 6.5. The corresponding amounts for capital costs were D46,670 and D26,138, for NBE and LRD respectively. In terms of total incremental provider costs, D572,515 and D337,607 were incurred in NBE and LRD respectively. In terms of cost distribution by health facility in NBE, Farafenni incurred the highest cost of D307,704 that comprised D284,911 and D22,793 for recurrent and capital costs respectively.

The facility with the lowest cost was Pallen Wolof with D26,532 (i.e. D24,296 for recurrent and D2,236 for capital). In the case of LRD, Soma had the highest cost with D159,330 that comprised D147,361 and D11,969 for recurrent and capital costs respectively. The facility with the least cost in LRD was Bureng with D22,512 (i.e. D20,654 for recurrent and D1,858 for capital costs). The average cost per patient ranged from D16.20-D16.74 with the lowest being the average cost per patient at Farafenni and the highest at Njaba Kunda. The details are as indicated in Table 6.5.

Table 6.5 Incremental IPTp cost to the provider per facility (Base case I)

Clinic	Multigravidae (n)	Total recurrent (D)	Total capital (D)	Total cost (D)	Average cost per patient (D)
North Bank East (NBE)					
Illiassa	1,994	30,091	2,951	33,042	16.57
No Kunda	2,169	32,686	3,211	35,897	16.55
Njaba Kunda	2,658	40,030	4,466	44,496	16.74
Farafenni	18,994	284,911	22,793	307,704	16.20
Kerewan	3,638	54,753	5,566	60,319	16.58
Ngeyen Sanjal	2,169	32,686	3,016	35,702	16.46
Sara Kunda	1,749	26,392	2,431	28,823	16.48
Pallen Wolof	1,609	24,296	2,236	26,532	16.49
Sub-total	**34,980**	**525,845**	**46,670**	**572,515**	16.37
Lower River Division (LRD)					
Soma	9,811	147,361	11,969	159,330	16.24
Sare Musa	2,401	36,183	2,929	39,112	16.29
Jalambereh	2,153	32,445	2,626	35,071	16.29
Bureng	1,366	20,654	1,858	22,512	16.48
DongoroBa	2,235	33,681	3,040	36,721	16.43
WellingaraBa	2,732	41,145	3,716	44,861	16.42
Sub-total	**20,698**	**311,470**	**26,138**	**337,607**	16.31
TOTAL	**55,678**	**837,315**	**72,808**	**910,122***	16.35

Source: Health facility costing study

* The difference between total costs in Tables 6.5 and 6.6 is due to rounding off in excel

6.3.2.1. Incremental cost of IPTp by input

Table 6.6 provides the total annual recurrent and capital cost profile of IPTp to the health provider. The total recurrent costs were estimated at D837,315 and the total incremental cost of introducing IPTp at all 14 clinics in the LRD and NBE was D910,123. The drugs (SP) needed for IPTp comprised the largest single cost component with 73% of the total incremental cost. The next most costly recurrent item was antenatal personnel cost at 14%. The overall recurrent cost component represents 92% of the IPTp implementation cost. Specifically, recurrent cost comprised, firstly, drugs, which are the 12 SP tablets per woman given over four antenatal clinic visits.

Also included in drug costs was a 10% provision for freight (since the drugs are usually purchased outside The Gambia) and another 10% for any wastage. Recurrent costs also consist of small items of equipment such as buckets and disposable plastic drinking cups, utilities, DHT and DoSH supervision and ferry crossing.

Table 6.6 Incremental provider cost of IPTp by input (Base case I)

Type of cost	Cost (D)	% of total
Recurrent costs		
Drugs	668,136	73.4
Materials and supplies	0	0.0
Small equipment	949	0.1
Utilities	3,341	0.37
Personnel:		
Antenatal	125,277	13.8
DHT	1,194	0.1
DoSH	6,681	0.7
DoSH ferry crossing	1,113	0.12
Vehicle Operations & maintenance	30,624	3.4
Sub-total	**837,315**	**92.0**
Capital costs		
Building	0	0.0
Transport	7,238	0.8
Equipment	10,447	1.1
Health Promotion	29,512	3.2
Training	25,611	2.8
Sub-total	**72,808**	**8.0**
Total cost of IPTp intervention	**910,123***	**100.0**

Source: Health facility costing study

According to the Health Mapping Study (Synergy International, 1999), outreach health facilities in the Gambia do not have utilities such as running water, electricity and telephone because they are usually located in remote rural areas where such amenities are not available. For this study, the only cost recorded under utilities was water, which was obtained from local wells. It is also assumed here that the use of other utilities such as electricity and telephone in some of the base health facilities (where they exist) will only vary slightly with IPTp and so would not affect cost. Utility costs other than those for water have therefore been omitted. The final recurrent cost category shown in Table 6.6 is the operation of vehicles and their maintenance. The cost per kilometre (CPK) method is used by Riders for Health (RFH) for estimating the depreciation, operation and maintenance costs of the Department of State for Health (DoSH) vehicles. RFH are an international NGO whose services are outsourced by the DoSH to manage and replace its transport fleet.

They use the specific amount of £0.48 (GBP) which is equivalent to D25.44 for every kilometre covered. The CPK includes all the running costs of the vehicle such as fuel, lubricant, maintenance, the driver's pay and vehicle depreciation.

The vehicle cost included at the intervention stage of IPTp considered only the additional kilometres and ferry crossing costs of the vehicle used by the supervisory team of the DoSH for their quarterly monitoring of IPTp. Although monitoring of programmes is routine in The Gambia, the introduction of new interventions usually means establishing special monitoring teams that comprise staff from the units involved in the implementation. The two units in the case of IPTp are Malaria Control and MCH. The use of the base facility trekking vehicle has not been included because regardless of whether IPTp is introduced or not, the usual monthly treks will continue to take place and would cover the same distances as when IPTp is introduced.

Capital costs include the depreciated cost of the DoSH trekking vehicle, equipment, health promotion and initial training. The overall capital costs represent only 8% of the total incremental direct costs. The costs of health promotion, initial training and equipment represent the three highest cost items with the lowest being transport. The cost of training health staff to properly administer IPTp as well as the cost of sensitising the public through health promotion was depreciated at a conventional discount rate of 3% with their respective useful lifetimes of two and four years. As already mentioned, the capital cost of clinic buildings has not been included because the existing facilities did not require any expansion to accommodate IPTp.

6.3.3 Results: Base case II - Recurrent and capital costs

The incremental recurrent cost to the provider incurred by 7,696 multigravidae who do not use bednets in NBE was D135,382 and the corresponding amount for LRD was D80,299 by 4554 multigravidae (details are in Table 6.7). The corresponding capital costs were D46,361 and D25,987, for NBE and LRD respectively. The total incremental costs for the two health divisions were D181,743 and D106,287 for NBE and LRD respectively. In terms of cost distribution by health facility in NBE, Farafenni again incurred the highest cost of D95,575 which comprised D72,967 for recurrent and D22,608 for capital costs. The facility with the lowest costs in NBE was Pallen Wolof with D8,552 (D6,329 recurrent and D2,223 capital). In the case of LRD, Soma had the highest cost with D49,655, comprising D37,743 recurrent and D11,912 capital costs. The facility with the lowest costs in LRD was Bureng with D7,253 (D5,408 recurrent and D1,845 capital). The average cost per patient ranged from D22.87-D25.31 with the lowest being the average cost per patient at Farafenni and the highest at Njaba Kunda.

Table 6.7 Incremental IPTp cost to the provider per facility (Base case II)

Clinic	Multigravidae (n)	Total recurrent (D)	Total capital D)	Total cost (D)	Average cost per patient (D)
North Bank East (NBE)					
Illiassa	439	7,809	2,937	10,746	24.48
No Kunda	477	8,473	3,191	11,664	24.45
Njaba Kunda	585	10,355	4,452	14,807	25.31
Farafenni	4,179	72,967	22,608	95,575	22.87
Kerewan	800	14,104	5,536	19,640	24.55
Ngeyen Sanjal	477	8,473	2,996	11,469	24.04
Sara Kunda	385	6,872	2,418	9,290	24.13
Pallen Wolof	354	6,329	2,223	8,552	24.16
Sub-total	**7,696**	**135,382**	**46,361**	**181,743**	23.62
Lower River Division (LRD)					
Soma	2,158	37,743	11,912	49,655	23.01
Sare Musa	528	9,362	2,914	12,276	23.25
Jalambereh	474	8,418	2,617	11,035	23.28
Bureng	301	5,408	1,845	7,253	24.10
DongoroBa	492	8,738	3,015	11,753	23.89
WellingaraBa	601	10,631	3,684	14,315	23.82
Sub-total	**4,554**	**80,299**	**25,987**	**106,287**	23.34
Total	**12,249**	**215,681**	**72,348**	**288,030***	23.51

Source: Health facility costing study

* The difference between total costs in Tables 6.7 and 6.8 is due to rounding off in excel

6.3.3.1. Incremental cost of IPTp by input

The total recurrent and capital costs were estimated at D215,681 and D72,348 respectively. The highest recurrent cost items were drugs at 51% and the lowest three were utilities (0.26%), DoSH ferry crossing costs (0.34%) and DHT supervision cost (0.4%). The second most costly recurrent item was vehicle operation and maintenance 10.6%. The overall recurrent cost component represents 75% (74.9%) of the IPTp implementation cost. Capital costs ranged from 2.4%-10.2% of the total IPTp costs, with the highest cost component being health promotion and the lowest, transport depreciation cost. The capital share of overall costs was 25% (25.1%). The total incremental cost of introducing IPTp at all the 14 clinics in the LRD and NBE was D288,029. The details of the cost profiles are in Table 6.8.

Table 6.8 Incremental provider cost of IPTp by input (Base case II)

Type of cost	Cost (D)	% of total
Recurrent costs		
Drugs	147,000	51.0
Materials and supplies	0	0.0
Small equipment	1,012	0.4
Utilities	735	0.26
Personnel:		
Antenatal	27,563	9.6
DHT	1,274	0.4
DoSH	6,616	2.3
DoSH ferry crossing	979	0.34
Vehicle Operations & maintenance	30,502	10.6
Sub-total	**215,681**	**74.9**
Capital costs		
Building	0	0.0
Transport	6,982	2.4
Equipment	10,486	3.6
Health Promotion	29,401	10.2
Training	25,479	8.8
Sub-total	**72,348**	**25.1**
Total cost of IPTp intervention	**288,029***	**100.0**

Source: Health facility costing study

6.4 DIRECT COST OF IPTp IMPLEMENTATION TO PATIENTS AND FAMILIES

As indicated earlier, IPTp was delivered through the existing antenatal clinics and so direct costs to women and those who accompany them to health facilities have mostly remained the same. However, the key difference between routine ANC and IPTp relates to the four visits required under IPTp compared with the average number of antenatal visits in the Gambia of 3.4 (Cham, 2003). Therefore, the direct cost of IPTp to women mainly comprises the additional fares women and their families pay to attend the health facilities and the out-of-pocket expenditure incurred at the facility for the extra 0.6 visit. Those who were accompanied to the health facility form a very small proportion of the sample size (n = 13). Therefore, the associated costs have minimal impact on overall direct costs. Furthermore, not all of those accompanied travelled by paid transport or spent money at the facilities. For these reasons, the costs related to those accompanied were dropped from the analysis. In the eight health facilities in North Bank East (Base and Outreach combined) where women were recruited into the trial, only six women indicated that they had incurred transport costs to attend Base facilities. The three base facilities were Farafenni (n = 4), Kerewan (n = 1) and Illiassa (n = 1).

No woman paid a fare to travel to any of the four outreach facilities in that health division. In the case of Lower River Division, out of two base facilities and four outreach facilities, only 10 women from base facilities and two from outreach facilities used transport to attend clinics. The majority of those who used transport attended Soma Major Health Centre (n = 9). It was assumed that those who used transport to go to the health facility would use the same means to return home.

In terms of out-of-pocket expenditure at the health facilities, 106 women spent an average of D336, attending base facilities in NBE. The corresponding figures for outreach facilities were 47 women and D117. The majority of those who spent money at the base facilities in NBE attended Farafenni (n = 62). As for the outreach facilities, the majority of the women attended Njaba Kunda (n = 25). In LRD, a total of 145 women attended base facilities, expending an average total expenditure of D575. The corresponding numbers for outreach facilities were 113 women and D226. The highest number of women who spent money at the facility attended Soma Health Centre (n = 95), with an average total expenditure of D475. For outreach facilities, the majority (n = 63) attended Jalambereh with an average total expenditure of D126.

In summary, of the 884 women recruited into the trial, only 18 paid a fare to go to health facilities. This represents 2% of the sample, with the remaining women travelling by unpaid means. The highest number of those who paid for transport attended Soma Health Centre (n = 9) followed by Farafenni (n = 4). Similarly, of the 884 women recruited, 411 (47%) women spent money at the health facility. The highest individual out-of-pocket expenditure was incurred at Soma (D628) followed by Farafenni (D202), then Jalambereh (D132).

6.4.1. Results: Base Case I - Direct cost of IPTp to patients

Using the same cost per woman, Table 6.9 shows that the total patient cost for IPTp per annum for NBE was D57,017 spent by 34,980 women. The corresponding figures for LRD were D33,738 and 20,698 women respectively. The total patient expenditure per annum was D90,755. Therefore, the total expenditure for a (0.6) additional visit for IPTp per annum was D54,453 spent by 55,678 women on fares and out-of-pocket expenses at the facilities. The average expenditure per woman for the extra 0.6 ANC visit was therefore D0.98.

Table 6.9 Total direct cost of IPTp to patients (Base case I)

Clinic	Multigravidae (n)	Total (D)
North Bank East (NBE)		
Illiassa	1,994	3,250
No Kunda	2,169	3,535
Njaba Kunda	2,658	4,333
Farafenni	18,994	30,960
Kerewan	3,638	5,930
Ngyen Sanjal	2,169	3,535
Sara Kunda	1,749	2,851
Pallen Wolof	1,609	2,623
Sub-total	**34,980**	**57,017**
Lower River Division (LRD)		
Soma	9,811	15,992
Sare Musa	2,401	3,914
Jalambereh	2,153	3,509
Bureng	1,366	2,227
DongoroBa	2,235	3,643
WellingaraBa	2,732	4,453
Sub-total	**20,698**	**33,738**
TOTAL	**55,678**	**90,755**
Total for 0.6 clinic visit		**54,453**
Average per woman		**0.98**

Source: Health facility costing study

6.4.2. Results: Base Case II - Total direct cost of IPTp to patients

Table 6.10 shows that the total patient cost for IPTp per annum for NBE was D12,547 spent by 7,696 women. The corresponding figures for LRD were D7,425 and 4,554 women respectively. The total patient expenditure per annum was D19,972. Therefore, the total expenditure for a 0.6 visit for IPTp per annum was D11,982 spent by 12,249 women on fares and out-of-pocket expenses.

Table 6.10 Total direct cost of IPTp to patients (Base case II)

Clinic	Multigravidae (n)	Total (D)
North Bank East (NBE)		
Illiassa	439	716
No Kunda	477	778
Njaba Kunda	585	954
Farafenni	4,179	6,812
Kerewan	800	1,304
Ngyen Sanjal	477	778
Sara Kunda	385	628
Pallen Wolof	354	577
Sub-total	**7,696**	**12,547**
Lower River Division (LRD)		
Soma	2,158	3,518
Sare Musa	528	861
Jalambereh	474	773
Bureng	301	491
DongoroBa	492	802
WellingaraBa	601	980
Sub-total	**4,554**	**7,425**
TOTAL	**12,249**	**19,972**
Total for 0.6 clinic visit		**11,982**
Average per woman		**0.98**

Source: Health facility costing study

6.5 INCREMENTAL COST OF IPTp IMPLEMENTATION

The total incremental cost of the IPTp intervention is the sum of the costs incurred by the provider, patients and families. The recurrent costs as a percentage of total direct costs represent 87% for Base case I and 72% for Base case II and the rest represent capital and direct costs to patients. Patient costs alone represent only 6% for Base case I and 4% for Base case II (see Table 6.11).

Table 6.11 Total direct IPTp implementation cost

	Base case I costs (D)	%	Base case II costs (D)	%
Provider				
Recurrent	837,315	87	215,681	72
Capital	72,808	8	72,348	24
Sub-total	**910,122**	**94**	**288,030**	**96**
Patients				
Direct	54,453	6	11,983	4
Sub-total	**54,453**	**6**	**11,983**	**4**
TOTAL	**964,576**	**100**	**300,012**	**100**

Sources: Tables 6.6, 6.8, 6.9 and 6.10

6.6. TREATMENT COSTS FOR LOW BIRTH WEIGHT AND ANAEMIA

Treatment costs comprise those expenses incurred by the provider, patients and families in treating LBW and anaemia at the AFPRCH and RVTH, including any referral costs.

6.6.1. Armed Forces Provisional Ruling Council Hospital (AFPRCH)

The treatment cost of anaemia at the AFPRCH comprises not only outpatient, but also inpatient treatment costs of the very severe anaemia patients who are referred from peripheral health facilities and admitted to the maternity ward.

6.6.1.1. Average referral cost from health centres to AFPRCH

The average distance from the seven health facilities within the trial site to the AFPRCH was 22 kilometres one-way, i.e. 44 kilometres for a return trip (Source: Head of Divisional Health Team (DHT), North Bank East and later Lower River Divisions). Given the poor road conditions, the average speed for health centre ambulances was a maximum of 50 kilometres per hour (health centre drivers), which means that a 44 kilometre referral to AFPRCH takes 0.88 hours (53 minutes). By using the D25.44 per kilometre payment to Riders for Health (RFH) for the use of health vehicles including ambulances, an average referral cost per patient to AFPRCH from the peripheral health centres within the trial site was D1,119. The cost per referral incurred for the use of a referral nurse for the round trip was D9.79. This is based on the hourly wage rate of D11.13, an eight-hour working day and 249 working days per annum, from an average annual income of D22,176 per annum.

6.6.1.2. Outpatient treatment cost of anaemia

The average outpatient treatment cost of anaemia was obtained by dividing the total cost obtained from the step-down analysis by the admission and outpatient visit cases (details in Table 6.12). The cost of treating one anaemia patient at the OPD/Accident and Emergency (A & E) which are usually combined at the AFPRCH was D271 per visit (Table 6.12). Since outpatient anaemia treatment requires four visits according to the Standard Treatment Guidelines (STG) (DoSH, 2001), the average cost to the provider for the four visits was D1,084.

6.6.1.3. Inpatient treatment cost of anaemia

The average inpatient cost per day in the wards at the AFPRCH ranged from D94 for Opthalmology (including eye theatre costs) to the most costly, D492, for Leprosy/Tuberculosis ward. Maternity had an average inpatient day cost of D421. The costs of these and a number of other wards are indicated in Table 6.12.

6.6.1.4. Average referral cost from AFPRCH to RVTH

The distance covered by an ambulance for a referral from AFPRCH to RVTH was 170 kilometres each way and 340 kilometres for a return trip (Mbaye et al, 2006). The cost per referral using RFH charges per kilometre of D25.44 was D8,650. It is policy at the AFPRCH that referrals of a reproductive health nature such as LBW and anaemia are accompanied by a nurse midwife (Source: Acting Chief Executive of AFPRCH). The cost per escort nurse for the six hours referral time is D66.78 per trip. The 10% allowance for the A & E assessment cost to the provider for those patients referred to RVTH through AFPRCH was D27.10.

Table 6.12 Unit cost of inpatient department and outpatient anaemia cases: AFPRCH

Inpatient & outpatient cost centres	Cost per admission/visit (D)	Cost per patient day (D)
Maternity	2,949	421
Opthalmology & Eye theatre	655	94
Medical ward	1,411	353
Surgical ward	5,736	191
Paediatrics	1,807	120
Leprosy/TB	29,507	492
OPD and A & E	271	-

Source: Step-down costing data.

6.6.2. Royal Victoria Teaching Hospital (RVTH)

The treatment cost of LBW and anaemia at the RVTH includes the inpatient care costs of VLBW, ELBW and very severe anaemia cases referred from the AFPRCH as well as the additional 10% allowance for the assessment cost at the A & E department.

6.6.2.1. Results: Inpatient treatment costs of VLBW and ELBW babies at RVTH

For the paediatrics ward, the average cost of admission, D2,364, was divided by the average length of stay (ALoS) of 15 days, giving the cost per patient day as D158 (Table 6.13). Therefore, the average inpatient day cost to the provider for VLBW treatment for the 21 days average length of stay was D3,318. The average inpatient day cost to the provider for an ELBW treatment was D4,424 for 28 days. The cost of assessment at the A & E was D35.60.

6.6.2.2. Inpatient treatment cost of very severe anaemia

To estimate the inpatient treatment cost of anaemia, the inflated 2003 cost of anaemia admission at the RVTH of D1,759 was divided by the ALoS for the maternity ward (seven days), which gives a cost of D251 per inpatient day, as indicated in Table 6.13.

Table 6.13 Unit Costs of Maternity and Paediatrics wards at the RVTH

Source & year	Ward	Per admission (D)	OPD (D)	A & E (D)	ALoS (days)	IP Day cost (D)
Fabricant & Newbrander (1994)	Maternity	1,132	109	22.9	7	162
	Paediatrics	1,521	109	22.9	15	102
2003	Maternity	1,759	169	35.6	7	251
	Paediatrics	2,364	169	35.6	15	158

Source: WHO/DoSH Gambia study (1995).

6.6.3. Direct outpatient and inpatient treatment costs of anaemia to patients and families at AFPRCH

The direct cost of hospital treatment to patients and their families includes any expenditure by or on behalf of the moderate and severe anaemia cases seen at the OPD and also for the very severe anaemia cases admitted to the maternity ward.

6.6.3.1. Direct outpatient treatment costs of anaemia to patients and families

Part A of Table 6.14 shows that the average fare paid per patient for a return trip to the AFPRCH for an outpatient visit was D21. Since all the patients observed were accompanied by one female escort who travelled by the same mode of transport, the fare paid for a return visit per escort for an outpatient visit was also estimated to be D21. In addition, a patient and escort paid D5 per trip on food and another D5 as user fees for the patient alone, an amount usually paid by every Gambian adult for an outpatient visit. The direct cost per outpatient visit to the patient was therefore D31. The average cost per visit including the costs incurred by both the patient and her escort was D52 (D31 and D21). Since the standard number of visits for the treatment of moderate and severe anaemia cases at the outpatient department was four (WHO, 1999), the direct cost for the full outpatient treatment of anaemia was estimated to be D208.

6.6.3.2. Direct inpatient treatment cost of anaemia to patients and families

The average daily expense incurred by a family on behalf of a very severe anaemia patient admitted at the hospital was D28.57. In addition, a weekly hospital bed fee of D25 per adult patient is paid by every Gambian. Since the average ALoS for the maternity ward (including for anaemia patients) was seven days (Chapter 7, Section 7.6.2), the cost of admission incurred by a family was the sum of the daily costs for seven days plus the hospital fees which together added up to D200. Details of the results are presented in part B of Table 6.14. It is assumed that the cost of transporting those patients who died at the hospital to their homes in either NBE or LRD is covered by cash gifts received at the hospital.

Table 6.14 Direct costs to patients and families for OPD and IP treatment for anaemia: AFPRCH

Hospital	Cost determinants	Fares (D)	Bed fees/ user fees (D)	Cash gift (D)	Out of pocket/ food (D)	Other (D)	Total (D)
A. AFPRCH	**Anaemia (Outpatient)**						
	Patient (n=66)	21.00	5.00	-	5.00	-	-
	Escort (n=66)	21.00	-	-	-	-	-
	Sub-total per trip	**42.00**	**5.00**	-	**5.00**	-	**52.00**
	Total for 4 trips	**168.00**	**20.00**	-	**20.00**	-	**208.00**
B. AFPRCH	**Anaemia (Inpatient) Non-fatal**						
	Patient (n=20)	-	25.00	-	-	-	-
	Escort (n=20)	-	-	-	N/A	N/A	-
	Female visitor (n=63)	2.00	-	4.00	3.50	3.00	-
	Male visitor (n=40)	2.00	-	4.00	3.50	3.00	-
	Sub-total per day	**4.00**	**3.57**	**8.00**	**7.00**	**6.00**	**28.57**
	Total for 7 days	**28.00**	**25.00**	**56.00**	**49.00**	**42.00**	**200.00**
	Fatal cases	**16**	**25.00**	**32**	**28**	**24**	**125**

Source: Hospital observation study.

6.6.3.3. Direct referral cost from health centres to AFPRCH

It was assumed that those patients referred from peripheral health centres used health facility ambulances at no direct cost to them or their families. It was said that health facilities staff ask families to contribute fuel for referrals but no such evidence was found at the AFPRCH or the surrounding health facilities.

6.6.4. Direct treatment cost to patients and families at the RVTH

The direct cost of hospital treatment to patients and their families includes any expenditure by or on behalf of VLBW and ELBW and very severe anaemia cases admitted at the paediatrics and maternity wards of the RVTH.

6.6.4.1. Direct inpatient treatment cost of VLBW to patients and families

The average cost incurred by family of a VLBW patient was D54 per day. This is shown in Section A of Table 6.15. The average inpatient treatment cost for a VLBW for the 21 days (ALoS) was D1,134. Since those who suffer from VLBW are usually infants of only a few days old, the weekly bed fees of D50 paid by anaemic mothers at the RVTH are waived for this category of patients. When successfully treated and then released home, the patient, his/her mother and the escort pay fare back to NBE or LRD. However, it was assumed that no new expenses were incurred for this as the amount was taken from the cash gifts received from the daily visitors (family and friends) at the hospital.

It was also assumed that the transport cost of a dead VLBW infant back to his/her home in NBE or LRD came from the same cash gifts. In practice, most of the infants who die at the RVTH are buried within the Greater Banjul Area (GBA) and in the process, save the family from costs related to transporting bodies to rural areas.

Table 6.15 Direct costs of LBW and Anaemia treatment to patients and their families: RVTH

Hospital	Cost determinants	Fares (D)	Bed fees/user fees (D)	Cash gift (D)	Out of pocket/food (D)	Others (D)	Total (D)
A. RVTH	**VLBW (Inpatient)** Non-fatal						
	Patient (n=8)	-	-	-	-	-	-
	Escort (n=8)	-	-	-	-	-	-
	Female visitor (n=50)	14.00	-	5.50	3.50	4.00	-
	Male visitor (n=21)	14.00	-	5.50	3.50	4.00	-
	Sub-total per day	**28.00**	-	**11.00**	**7.00**	**8.00**	**54.00**
	Total for 21 days	**588.00**	-	**231.00**	**147.00**	**168.00**	**1134.00**
	Fatal case	**196.00**	-	**77.00**	**49.00**	**56.00**	**378**
B. RVTH	**ELBW(Inpatient)**						
	Patient (n=4)	-	-	-	-	-	-
	Escort (4=4)	-	-	-	-	-	-
	Female visitor (n=30)	14.00	-	5.50	3.50	4.00	-
	Male visitor (n=12)	14.00	-	5.50	3.50	4.00	-
	Sub-total per day	**28.00**	-	**11.00**	**7.00**	**8.00**	**54.00**
	Total for 28 days	**784.00**	-	**308.00**	**196.00**	**224.00**	**1512.00**
	Fatal case	**140.00**	-	**55.00**	**35.00**	**40.00**	**270.00**
C. RVTH	**Anaemia (Inpatient)**						
	Patient (n=15)	0.00	50.00	-	-	-	-
	Escort (n=15)	0.00	-	-	-	-	-
	Female visitor (n=38)	14.00	-	5.50	3.50	4.00	-
	Male visitor (n=12)	14.00	-	5.50	3.50	4.00	-
	Sub-total per day	**28.00**	**7.14**	**11.00**	**7.00**	**8.00**	**61.14**
	Total for 7 days	196.00	50.00	77.00	49.00	56.00	**428.00**
	Fatal case	112.00	50.00	44.00	28.00	32.00	**266**

Source: Hospital observation study.

6.6.4.2. Direct inpatient treatment cost of ELBW to patients and families

The daily cost incurred by the relatives of a patient in the case of ELBW was D54. Therefore, the total, including cash gifts, for the four weeks (28 days) was D1,512 (as shown in Section B of Table 6.15).

6.6.4.3. Direct inpatient treatment costs of anaemia to patients and families

Those very severe anaemia cases admitted at the RVTH paid a weekly bed fee of D50 for the average seven-day stay and their families incurred daily expenses of D54, in the case of VLBW and ELBW. This gave a total of D428 for a seven-day stay. The details are shown in Section C of Table 6.15.

6.7. SUMMARY

The direct cost of IPTp for the year 2003 was explored in terms of costs incurred by the provider, patients and their families. The total incremental cost for the provider was D910,123 and direct cost to patients was D54,453. Together, this gave a total direct cost of IPTp of D964,576 for Base case I (the total multigravidae population). The corresponding values for Base case II (the multigravidae population who do not use bednets) were D288,029, D11,983 and D300,012. The average cost per patient ranged from D16.20-D16.74 in Base case I, with the lowest being the average cost per patient at Farafenni and the highest at Njaba Kunda. The average cost per patient in Base case II ranged from D22.87-D25.31 with the lowest being the average cost per patient at Farafenni and the highest at Njaba Kunda health facilities. Treatment costs to the provider of LBW and anaemia were calculated for use later in the analysis.

CHAPTER 7: RESULTS II: INDIRECT COSTS OF IPTp

7.1. INTRODUCTION

The aim of this chapter is to measure and value unpaid work by women in rural villages and towns in NBE and LRD. Town in this case refers to those busy commercial centres located in the study area such as Farafenni and Soma. The chapter deals with the use and organisation of time by women within the reproductive age group (15-49 years). The time use measured for each household activity is converted into monetary values using four different approaches. The values obtained using the opportunity cost approach are then used to estimate the indirect costs of the IPTp intervention as well as the unit indirect costs of treating LBW babies and anaemic mothers at the Armed Forces Provisional Ruling Council Hospital (AFPRCH) and the Royal Victoria Teaching Hospital (RVTH).

This chapter is arranged into seven sections. Section 7.2 presents the results of the household time use survey in terms of the main (primary) activities. Section 7.3 presents the comparative analysis of time use results in terms of villages and towns, health divisions, season of the year and the day of the week. In Section 7.4, the value of time was estimated in hourly wage rate for women for various household tasks, and selected wage rates for men in the study setting. Four different approaches are then used to value time. Section 7.5 uses the wage rates calculated in Section 7.4 to estimate the indirect costs of IPTp intervention, and the indirect costs of treating LBW babies and anaemic mothers in 7.6. The treatment costs estimated were the unit indirect cost of treating anaemia at AFPRCH (outpatient and inpatient) and LBW and anaemia at RVTH (inpatient only) plus any referral costs between peripheral facilities, AFPRCH and RVTH. The chapter ends with a brief summary of the main findings in Section 7.7.

7.2 TIME USE RESULTS

This section presents the results of household time use activities in The Gambia with a view to contextualising the household data. This is necessary because activities that are usually included as part of unpaid work vary from one society to another, often depending on a country's level of development (Goldschmidt-Clermont, 1982, 1987).

7.2.1. Time use indices

Most time use analyses are based on the six indices shown in Table 7.1, defined according to their numerators and denominators (van den Broek, 2004, ESCAP, 2003). The two important estimates are the number of persons in the survey population and the number of survey participants engaged in the activity during the course of the day. The total number in the study population remains the same while the number of participants changes depending on which activity one considers.

Measure (i) is the average duration of activity per person in the population, while (vi) refers to the average duration per activity per participant in that activity. The same interpretation applies to (ii) and (v) but using episodes instead of participants. The proportion of participants to total population (iii) is called the 'participation rate'. The participation rate, which is a proportion, is the number of persons who actually spent time doing a particular activity divided by the total survey population comprising those who actually used time for the activity as well as those who used zero time (van den Broek, 2004, ESCAP, 2003). For the purpose of this work, only indices (i) and (iii) were used. The main reason for measuring and valuing time use in this thesis was to be able to value unpaid work and therefore the two indices identified, adequately serve that purpose. The first gives a detailed measurement of time use while the second determines the extent of women's participation in a particular activity.

Table 7.1 Time use indices

Denominator of Index	Numerator of Index		
	Total duration of activity	Total number of episodes of activity	Total number of persons doing activity
Total number of persons (population)	(i) Duration	(ii) Episodes	(iii) Participants
	All persons	All persons	All persons
Total number of persons doing activity (doers/participants)	(iv) Duration	(v) Episodes	
	Participants	Participants	
Total number of episodes of activity	(vi) Duration		
	Episodes		

Source: Adapted from ESCAP, 2003.

The presentation of results of the time use study takes two forms. First, the main activities were all ranked from the most time-consuming to the least time-consuming. According to the American Time Use Study (2005), it is a fact of life that people engage in more than one activity at a time and the major activity they perform at a specific time is known as the main or primary activity. In the case of this study, the main activities represent those activities the women were observed doing during the household survey. Those activities performed alongside the main activities are referred to as 'parallel' or 'secondary' activities (UNSD, 2005). For the purpose of this study, only main activities were considered. Similarly, in paid work, people spend part of their time multi-tasking and part in focused activity. They are normally paid for the main activity only.

Second, activities were then classified using the standard United Nations classification system (ICATUS) as outlined in Section 5.10.4 and Appendix 10. For the purpose of this study, ICATUS has been adapted deliberately to reflect the types of unpaid work that are common in The Gambia. Instead of the 10 groups, only seven (2, 3, 4, 6, 8, 9 and 10) were relevant for the study setting. The childcare component of Group 5 was incorporated into Group 4. The composition of the groups is outlined below while the adapted classification for The Gambia is presented in Table 7.2.

Personal activities include bathing, seeking medical care, sleeping, eating and dressing. Mass media includes listening to radio, and where available, watching television. Listening to the radio is classified as a main activity by the UN classification scheme, but in most countries, listening to radio and even a good deal of television watching time is a secondary rather than primary activity. As the name implies, income includes any income-generating activities such as selling at the local markets or being engaged in some kind of paid work or schooling. Socio-cultural activities include receiving visitors, visiting others, parties and meals with people at home; making telephone calls during free time and community includes community work, meetings of political or religious nature and any travelling related to them. Finally, the time spent on main activities was compared across days of the week, villages and towns, health division (LRD or NBE); and season of the year.

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ısehold[10]	Community[11]	Socio-cultural[12]	Mass media[13]	Personal[14]
›king	Meetings/ceremonies	Meetings/ceremonies	Radio/TV	Bathing/dressing
ındry	Travelling	Receiving Guests		Chatting/Attaya
ınding		Visiting neighbours		Eating
paring food		Travelling		Medical care
:al shop/market				Plaiting
:eping				Praying
shing dishes				Resting/sleeping/ill
:hing firewood				Rest room
:hing water				Travelling
ldcare				
.er household work				

0).

ırmal)
uction of goods (informal)
ıent and shopping for own household
ther households: such as village meetings, community work etc
tenings, weddings, political meetings, religious meetings,

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7.2.2. Main activities

The time use data obtained from the observation study are presented in Table 7.3. Column (1) represents the categories of main activities. Column (2) represents the non-zero respondents for a particular activity (i.e. those who spent any time on a particular activity). Column (3) represents the zero respondents for an activity (i.e. those who did not spend time in a particular activity). Mean time use in hours is shown in column (4) (i.e. the average time use for those who actually undertook a particular activity during the survey week). Mean time is estimated using only those women who engaged in the particular activity on the week of the survey. Column (5) is the participation rate, which is the proportion of those who used time for an activity over the sample size (i.e. sum of non-zero and zero respondents). Mean time use in hours, shown in column (6), is the average time use for both those who actually undertake a particular activity and those who indicated zero time for the same activity. This is the average hours spent per day performing a particular activity, representing the time use by all those women observed during the survey week, including those who did not perform the particular activity (ATUS, 2005). It reflects the number of women engaged in an activity and the duration of time spent performing those activities. The last three columns (7, 8 and 9) represent the minimum, maximum and the sum of time use per activity respectively.

The mean daily time use for main activities according to the study was 12.7 hours per day during the dry season. The time range per activity was 0.001-2.8 hours with the lowest being the time taken to listen to radio or watch television (participation rate of 0.003) and the highest being the time taken to cook for the family (participation rate of 0.9). Unlike their counterparts in the urban areas where women normally cook twice a day, it is not uncommon for rural families to cook different dishes for the three meals (breakfast, lunch and dinner). The time-consuming nature of cooking in this setting may be a result of using firewood, which takes a long time to burn. This is especially true during the rainy season when the wood is often wet.

Table 7.3 Main household activities

Main activities (1)	None- zero respondents (2)	Zero respondents (3)	Mean time use (hours) (4)	Participation rate (5)	Mean time (hours) (6)	Min. (hours) (7)	Max. (hours) (8)	Sum (hours) (9)
Cooking	281	34	3.2	0.9	2.8	0.3	8	892
Farming	105	210	4.6	0.3	1.5	0.2	9	487
Resting/ sleeping	247	68	1.9	0.8	1.5	0.1	7	465
Fetching water	267	48	1.2	0.8	1.0	0.1	4	319
Laundry	120	195	1.6	0.4	0.6	0.1	6	190
Pounding	125	190	1.2	0.4	0.5	0.2	5	154
Eating	280	35	0.5	0.9	0.5	0.1	2	148
Chatting	98	217	1.5	0.3	0.5	0.1	10	146
Meeting/ ceremonies	52	263	2.7	0.2	0.4	0.5	9	141
Sweeping	231	84	0.6	0.7	0.4	0.1	4	132
Market (Lumo)	46	269	2.8	0.1	0.4	0.3	9	130
Gardening	61	254	1.7	0.2	0.3	0.2	6	104
Other household work	87	228	1.1	0.3	0.3	0.1	6	100
Visiting neighbours	81	234	1.1	0.3	0.3	0.1	4	88
Bath/dress	189	126	0.4	0.6	0.2	0.1	1	72
Childcare	142	173	0.5	0.5	0.2	0.1	2	71
Medical care	22	293	2.8	0.1	0.2	0.6	10	61
Fetching firewood	35	280	1.5	0.1	0.2	0.1	6	51
Travelling	9	306	5.6	0.0	0.2	2.1	11	51
Washing dishes	125	190	0.4	0.4	0.2	0.1	2	48
Local shop/ Market	46	269	0.9	0.1	0.1	0.1	3	41
Preparing food	25	290	1.2	0.1	0.1	0.2	4	29
Plaiting	11	304	2.3	0.0	0.1	1.0	6	25
Receiving guests	24	291	0.8	0.1	0.1	0.2	3	20
Praying	42	273	0.3	0.1	0.04	0.1	1	12
Rest room	33	282	0.3	0.1	0.03	0.1	2	11
Livestock rearing	3	312	1.3	0.01	0.01	0.7	2	4
Radio/TV	1	314	0.2	0.003	0.001	0.2	0.2	0.2
Total			**44.1**		**12.7**			

Source: Household observation study.

The most time-consuming work-related activities apart from cooking were farming, with 1.5 hours per day at a participation rate of only 0.3, and fetching water, which had an average time use of 1.0 per day at a participation rate of 0.8. The farming sector contributes 20-25% of GDP, provides food, is a primary source of export earnings, provides inputs for agro-industry and has well-established linkages with other sectors especially tourism (CSD, 1995). Fetching water can be time-consuming and so occupies a big chunk of women's time. This is even more apparent in places where people depend on water from deep wells for their survival. The most common source of daily water is traditional wells that are several metres deep. More than one-third of Gambian women living in rural areas use wells as their main source of water (CSD, 1995). Laundry and pounding were next with respective times of 0.6 hours and 0.5 hours per day. Unlike other household work, laundry is not done on a daily basis in villages and towns but rather on specific days. Some communities consider it taboo to wash their clothes on certain days. Ironing has a direct relationship with laundry and is practised in almost all localities. Carrying out basic household work, including ironing, is seen as a sign of responsibility for women. Like any other unpaid household work, pounding occupies the time of rural women. Although the government and NGOs, such as the Catholic Relief Services (CRS), have made efforts to replace this labour intensive practice with grinding machines, pounding remains common in The Gambia. The remaining main activities took between 0.001 and 0.5 hours per day as shown in Table 7.3.

7.2.3. Classification of main activities

Table 7.4 and Figure 7.1 show that 'household work' recorded the highest time use with an average time of 6.4 hours per day during the dry season. This was followed by 'personal activities' with an average time use of 3.3 hours per day. Mass media recorded the least time with only 0.001 hours. Farming took up 1.8 hours per day. This comprises farming itself (1.5 hours), gardening (0.3 hours) and livestock rearing (0.01 hours). Farming in The Gambia is rain-fed and therefore mostly done during the rainy season. However, the fact that the household time use survey was conducted very close to the rainy season could have accounted for the 1.5 hours farming time. Women use months close to the rainy season to prepare their fields in readiness for planting. Time use for income-generating activities, community activities, and socio-cultural activities all fell below one hour.

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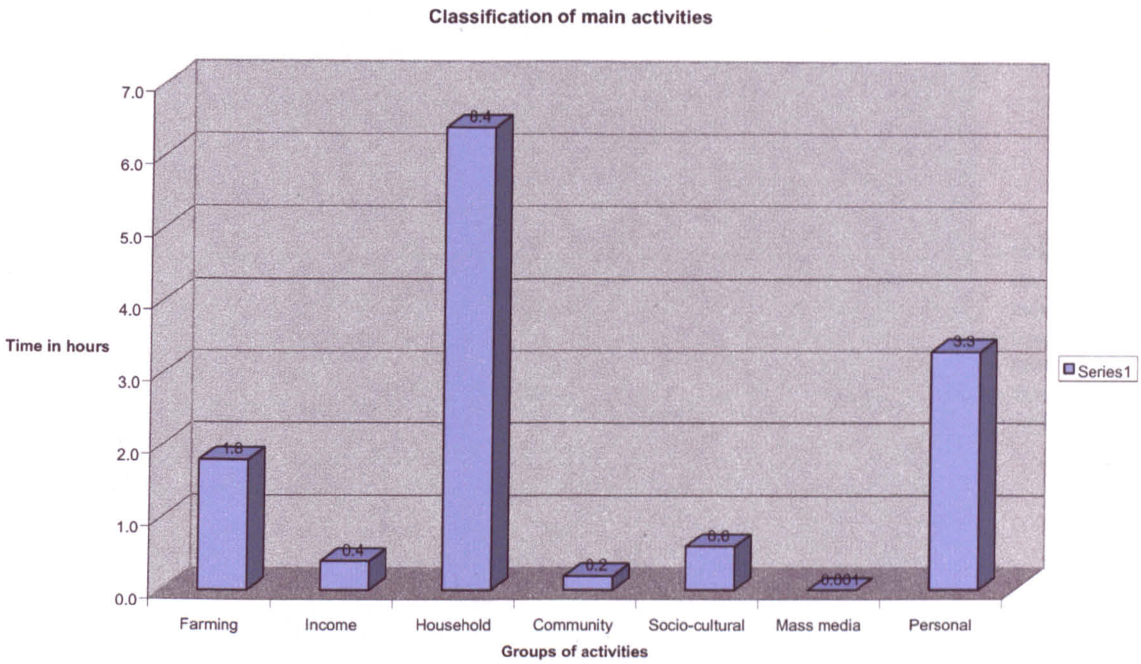
in hours per day

Household	Time use (hours)	Community	Time use (hours)	Socio-cultural	Time use (hours)	Mass media	Time use (hours)	Personal	Time use (hours)	
Cooking	2.8	Meetings/ Ceremonies	0.2	Meetings/ ceremonies	0.2	Radio/TV	0.001	Bathing/dressing	0.2	**5.3**
Laundry	0.6	Travelling	0.0	Receiving guests	0.1			Chatting/Attaya	0.5	**1.5**
Pounding	0.5			Visiting neighbours	0.3			Eating	0.5	**1.31**
Preparing food	0.1			Travelling	0.0			Medical care	0.2	**0.3**
Local Shop/market	0.1							Plaiting	0.1	**0.2**
Sweeping	0.4							Praying	0.04	**0.44**
Washing dishes	0.2							Resting/sleeping/ill	1.5	**1.7**
Fetching firewood	0.2							Rest room	0.03	**0.23**
Fetching water	1.0							Travelling	0.2	**1.2**
Childcare	0.2									**0.2**
Other household work	0.3									**0.3**
	6.4		**0.2**		**0.6**		**0.001**		**3.3**	**12.7**

Figure 7. 1 Time use by main activities in hours



Source: Observation study.

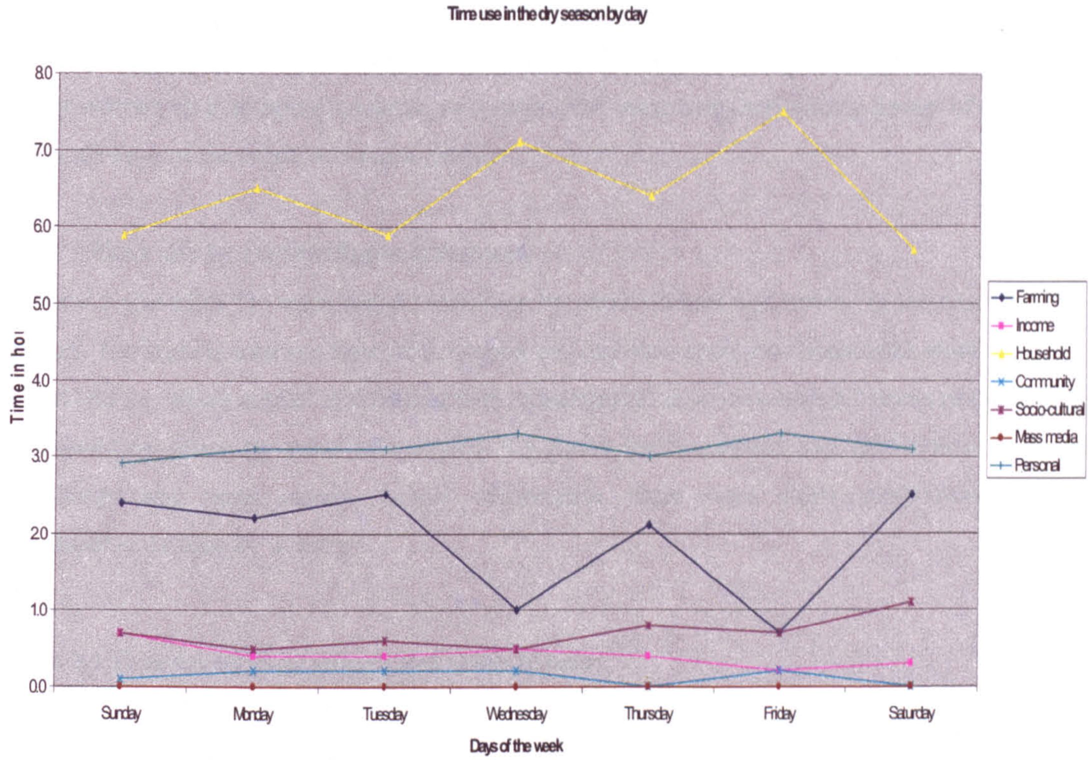
7.3. COMPARATIVE ANALYSIS OF TIME USE

The aim of this section is to conduct sub-group analyses of the time use data presented in Section 7.2.3, Table 7.4. The sub-groups analysed include time use by day of the week, by rural villages and towns, by health division and by season.

7.3.1. Day of the week

The main activities have been classified by day of the week, as illustrated in Figure 7.2. It was shown in Figure 7.1 and Table 7.4 that household work was the most time-consuming activity, with an average daily time use of 6.4 hours. This varied by day. Household time use for the same group of activities on Wednesday and Friday were 7.1 hours and 7.5 hours respectively, while farming for the same days were only 1.0 hours and 0.1 hours.

Figure 7.2 Time use by day of the week in the dry season in hours



Source: Household observation study.

These two days happen to be free days from farm work for most rural women. The reason for not working on farms on Wednesdays is that, traditionally, this day is regarded as a day of rest in rural communities (source: community leaders). Being a predominantly Muslim country, Fridays are usually set aside for prayers. However, since not all the women within the sample share the same culture or practise the same religion, time has been recorded for farming on these two days.

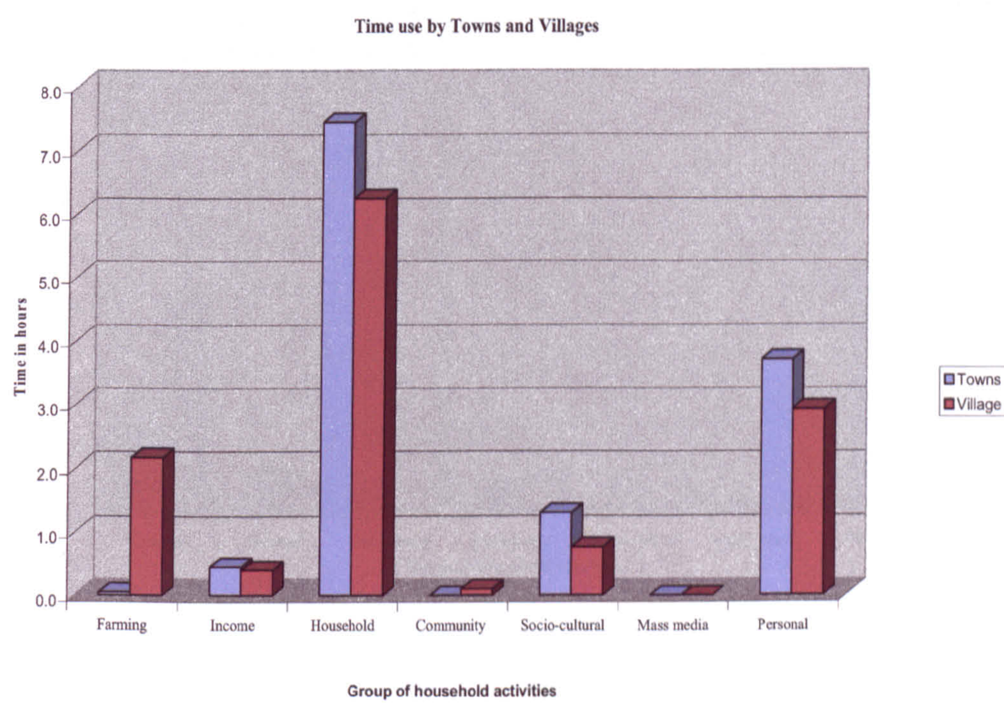
The second most time-consuming activity was 'personal time', at approximately three hours per day. One of the most important components of personal time was the time spent chatting and drinking 'Attaya'. The most time-consuming days for farming were Saturday and Tuesday, each incurring 2.5 hours, followed by Sunday with 2.4 hours. The relationship between household work and farming on Wednesdays and Fridays is inverse.

While household work is highest on these two days, subsistence farm work is lowest. It is clear that women work a consistent amount of time on most days of the week, but the nature of the work shifts from farm work to household work on Wednesdays and Fridays. The reason for this is that women stay at home on these two days. The least time-consuming group of activities across all days of the week was mass media.

7.3.2. Time use by rural villages and towns

Figure 7.3 classifies the main unpaid activities by rural villages and towns. In the case of rural villages, the highest average time of 6.3 hours per day was spent on 'household work' and the lowest was on 'Mass media' at 0.04 and then 'community' activities with 0.1 hours per day. The corresponding times for rural towns were 7.5 hours for household and zero hours for both community and mass media. Across settlements, there were slight differences in the prioritisation of time by activity.

Figure 7.3 Time use by rural villages and towns in hours

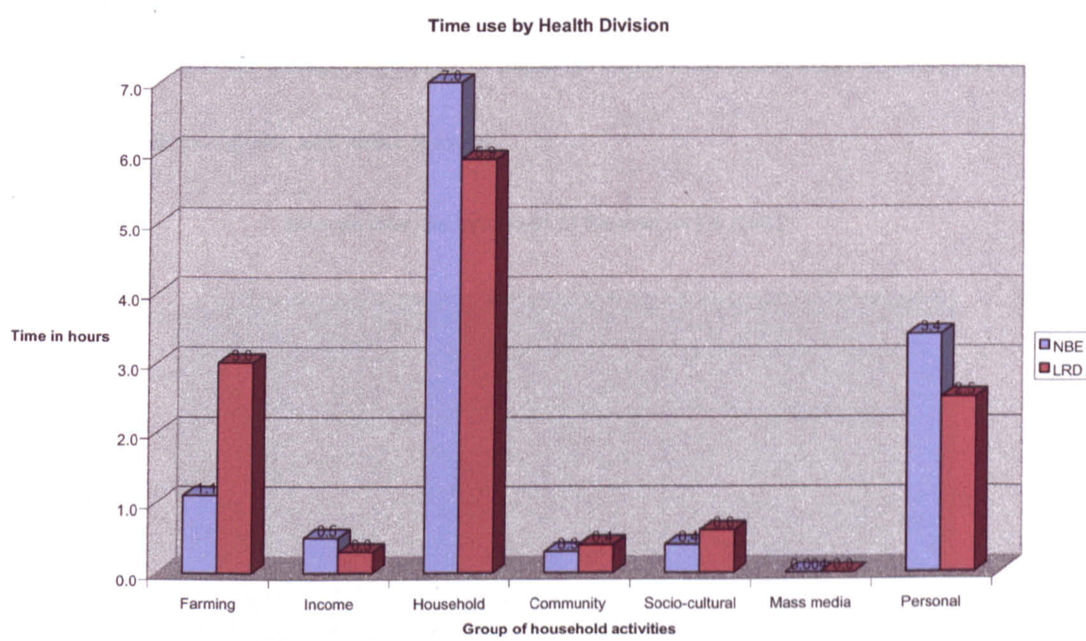


Source: Observation study.

7.3.3. Health Division - NBE and LRD

Figure 7.4 shows the activities classified by Health Division; it presents the average time use per division. In NBE, the most time-consuming group of activities was again household work, with an average daily time use of 7.0 hours. The least time-consuming activity was mass media with an average time use of 0.04 hours per day. The corresponding figures for LRD were 5.9 hours for household work and 0.0 hours for mass media. Looking in more detail, cooking came top in NBE with an average time of 2.9 hours per day at a participation rate of 0.9. At the lowest end was radio/television with an average time use of 0.001 hours per day at a participation rate of 0.01. In the case of the LRD, cooking and farming ranked first with an average time use of 2.7 hours per day, with respective participation rates of 0.9 and 0.5. Lowest on the ranking was praying, with an average time use of 0.001 hours per day at a participation rate of 0.008.

Figure 7.4 Time use by Health Division

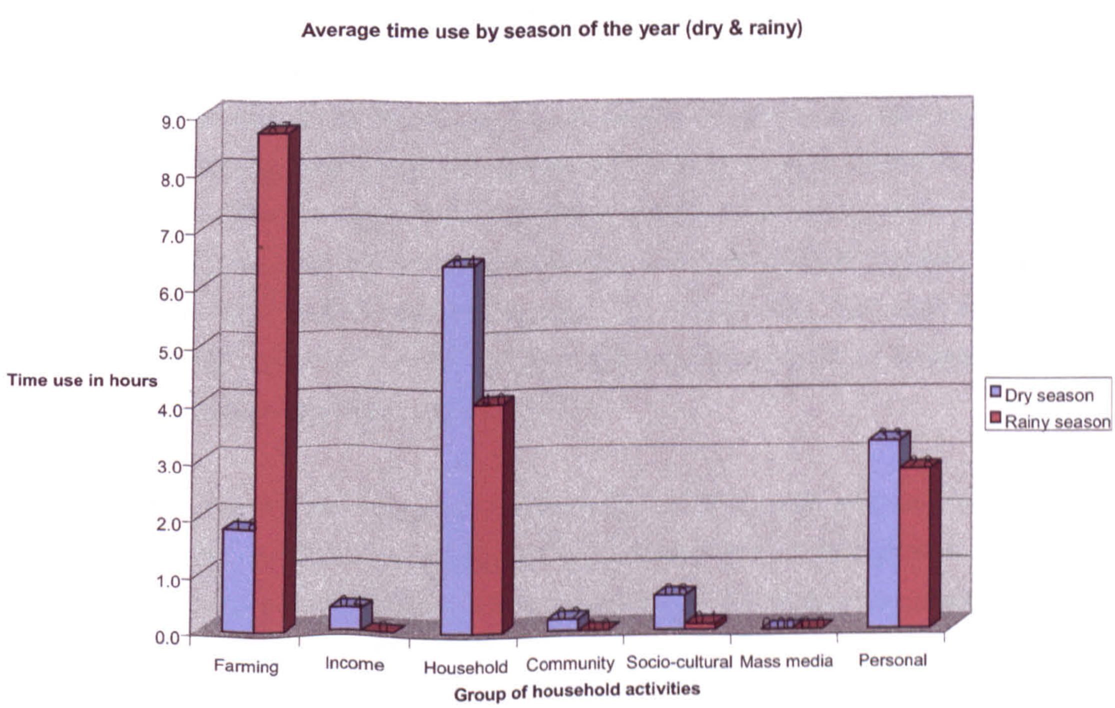


Source: Observation study.

7.3.4. Season

Since the observation data were collected during the dry season, it was necessary to collect time use data for the rainy season as well. The method used to collect this data was explained in Chapter 5, Section 5.10.4. Figure 7.5 compares the average daily time use by season of the year. The prioritisation of time use altered between seasons. The highest-ranking group of activities changed from household work (6.4 hours per day) in the dry season to farming in the rainy season (8.7 hours per day). Household work time decreased from 6.4 hours in the dry season to 4.0 hours per day in the wet season. The time used for personal activities also dropped from 3.3 hours per day in the dry season to 2.8 hours per day in the rainy season. Similarly, the time allocated to community activities dropped from 0.2 hours to zero and that for socio-cultural from 0.6 hours to only 0.1 hours. All these activities were sacrificed in favour of farming during the rainy season. Since the two seasons are of equal duration (six months each), in terms of workloads, the average of the two was estimated. Farming and related activities had the highest average time with 5.3 hours per day, closely followed by household activities with 5.2 hours per day. The group with the lowest time use again was mass media with an average time use of 0.0005 hours. All other groups fell between household (5.2 hours) and mass media (0.0005).

Figure 7.5 Time use by dry and rainy seasons



Source: Household observation study.

7.3.5. Summary

This section of Chapter 7 has reviewed different methods of measuring time use and uses a combination of methods to measure unpaid work in rural Gambia. From the results, cooking tends to attract more time followed by farming. The most time-consuming activity during the rainy season is farming. Cooking tends to be the most time-consuming pursuit in the dry season. In terms of time use by settlement, household work and petty trading are more common in the towns compared to farming in the villages. The result of the various sub-group analyses showed that the only comparison that produces disparity in time use was the analysis by season of the year. Henceforth, the combined average of the two seasons (dry and rainy) was used to estimate the indirect costs for IPTp intervention and any treatment of LBW babies and anaemic mothers.

7.4. VALUATION OF UNPAID WORK

The next sections are devoted to valuing unpaid work in monetary terms. Sections 7.4.1 and 7.4.2 present the wage rates for women and men respectively, followed by the rates of pay for certain types of household work within the study setting. In Section 7.4.3, the time use data is used to calculate household work value using four methods. The values obtained are used to estimate the indirect costs of IPTp intervention and hospital treatment for LBW and anaemia. Details of the methods of valuation used are presented in Section 5.11, Chapter 5.

7.4.1. Wage level for women

Table 7.5 presents the average hourly pay rates for female workers in the study area. The table was generated after collecting data on monthly pay, number of days worked as well as the number of hours worked per day. The top four wage rates (i.e. two cash payment only and two cash and in-kind payments) will be further explained. In the case of market traders, the average number of days they work in a month is around 26 because they take only Sundays off. Dividing the daily income of D170 by 11 (the number of hours spent on income-generating activities) gives an average hourly rate of D15.45.

Uneducated day care workers are paid a monthly salary of D900 and in turn, they work for 16.3 days, which gives a daily pay rate of D55.21. Based on their daily work regime of eight hours, their hourly pay rate was estimated at D6.90. In addition to the financial remuneration, carers also benefit from in-kind payment, which in this case is one meal per day. The estimated cost of the meal, lunch, was D12 and the hourly rate of in-kind payment alone was D1.50.

Therefore, the average hourly pay rate for a day carer, including in-kind payments, was D8.40. The monthly rate of pay for laundry was D400. Based on four different laundry days each lasting 12 hours (including ironing), the hourly rate of pay was estimated at D8.33.

Another potential form of employment for women in rural Gambia is cooking at schools such as lower basic or basic cycles (formally primary & secondary), Madrassa and early childhood development schools, and health facilities. The remuneration for each category is presented in Table 7.5. From the survey results, it was revealed that school cooks work 196 days in a year and are usually paid one 50-kilogramme bag of rice per month for nine months in a year. These in-kind payments are usually from the school food supply normally given by the World Food Programme (WFP). The average length of the school term in The Gambia is 13.8 weeks, which translates into a total of 41.5 weeks in one academic year.

Since there are five school days in a week, and the number of public or school holidays in the country is 11, it gives 196 working days in a year. Taking the market value of the nine bags of rice at D700 per bag and converting it to an hourly pay rate gives an average of D5.37. Since the cooks also benefit from free lunch at the school, the value of that in-kind benefit has also been taken into account for the 196 days they work and was equivalent to D2.00 per hour. Combining the average hourly rate of the two in-kind benefits the cooks receive gives an overall average hourly rate of pay of D7.37. The hourly wage rates for other less common types of work are also presented in Table 7.5.

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male labour including benefits in-kind in rural Gambia.

Monthly ay/income (D)	Daily pay (D)	Hours work per day	Hourly cash pay (D)	Description of in-kind payment	Quantity	Amount per year (D)	Amount per day (D)	Hourly in-kind pay (D)	Average pay per hour (D)
-	170.0	11	15.45	None	-	-	-	-	**15.45**
900	55.21	8	6.90	Meals	1		12.00	1.50	**8.40**
400	100	12	8.33	None	-	-	-	-	**8.33**
-	None	6	0.00	50 kg bag of rice	9	6,300	32.21	5.37	
-	-	6		Meal	1	-	12.00	2.00	**7.37**
-		-	6.00	None	-	-	-	-	**6.00**
-	-	-	5.93	None	-	-	-	-	**5.93**
454	17.46	9	1.94	Meals	3	-	29	3.22	**5.16**
700	26.92	11	2.45	Meals	3	-	29	2.64	**5.09**
-		-	5.00	None	-	-	-	-	**5.00**
-		-	5.00	None	-	-	-	-	**5.00**
758.4	29.17	8	3.65	None	2	-	-	-	**3.65**
-	19.38	11	1.76	Meals	2		17	1.55	**3.31**
-	19.38	8	2.42	None	2	250	0.80	0.10	**2.52**
-	19.38	8	2.42	None	2	250	0.80	0.10	**2.52**
-	19.38	8	2.42	Uniform	2	250	0.80	0.10	**2.52**
									5.75

ata from health and other institutions.

7.4.2. Wage level for men

As is the case in Section 7.4.1 and Table 7.5, Table 7.6 presents the average hourly pay rates for male workers in the study area. The table was generated after collecting data on monthly pay, number of days worked as well as the number of hours worked per day. The top four wage rates (i.e. two cash payment only and two cash and in-kind payments) are further explained. Shepherds who look after cattle in the study area normally work for an average of 30.4 days per month for 12 hours per day. They in turn have the full milk product of the cattle at their disposal as their pay. The Shepherds realised an average of three gallons per herd of cattle and each gallon was sold for D35, giving an average daily total of D105. Translating that to an hourly pay rate gave D8.75.

School caretakers normally work for 196 days in a year, eight hours a day with an average monthly pay of D653 (D550 pay and 103 allowance). In addition to their pay, they also benefit from one lunch every school day, worth D12. Translating this into a monetary value gave an average hourly pay rate of D6.51. The hourly cash pay rate for a farm labourer was D5.17 (i.e. D31 for six hours of work per day).

The hourly cash pay rate for a taxi driver was D2.62 based on the monthly pay of D889 for 26.1 days and a 13-hour work regime. In terms of in-kind payment, they benefited from three meals at D29 per day, which translated to D2.23 per hour. Combining the two, gave the average hourly rate of payment of D4.85. The average hourly pay rates for all the remaining types of work typically carried out by men in the study area are indicated in Table 7.6. They include health facility cleaners, bakers at AFPRCH, farm labourers, garden labourers, market cleaners and watchmen. The average hourly pay rate across all forms of work in the study area was D3.86.

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ale labour including benefits in-kind in rural Gambia.

onthly pay (D)	Daily pay (D)	Hours work per day	Hourly cash pay (D)	Description of in-kind payment	Quantity	Amount per year (D)	Amount per day (D)	Hourly in-kind pay (D)	Average pay per hour (D)
-	-	12	-	gallons of milk	3	38,325	105	8.75	8.75
653	40.06	8	5.01	Lunch	1	-	12	1.50	6.51
-	31	6	5.17	None	-	-	-		5.17
889	34.06	13	2.62	Meals	3	-	29	2.23	4.85
-	28.69	8	3.59	None	-	-	-	-	3.59
-	28.69	8	3.59	None	-	-		-	3.59
479	18.42	11	1.67	Meals	2	-	17	1.55	3.22
582	22.38	8	2.80	None	-	-	-	-	2.80
-	19.38	8	2.42	None	2	250	0.80	0.10	2.52
-	19.38	8	2.42	Uniform	2	250	0.80	0.10	2.52
-	19.38	8	2.42	Uniform	2	250	0.80	0.10	2.52
-	19.38	8	2.42	Uniform	2	250	0.80	0.10	2.52
-	19.38	12	1.62	None	-	-	-	-	1.62
									3.86

ata from health and other institutions.

7.4.3. Results of valuation

Table 7.7 shows women's time for potential wage earning activities. The average time use by a woman per day is 5.3 hours on subsistence work such as farming, gardening and livestock rearing and 0.2 hours on income-generating activities such as selling produce at the market. The household component is 5.2 hours. The three components together give a total time use of 10.7 hours per day.

Table 7.7 Daily pattern of unpaid time use

	Farming (hours)	Income generating work (hours)	Unpaid household work (hours)	Total unpaid time use (hours)
Total	5.3	0.2	5.2	**10.7**

Source: Household observation study, Section 7.3.4 and Figure 7.5

As described in Section 5.11, an input-based approach was used, and the four methods for valuing unpaid work — opportunity cost, replacement cost, human capital, and fictional cost — applied by using the appropriate wage rates as shown in Table 7.8 to derive average hourly wage rates for women, men and for both men and women. These are D5.79, D3.83 and D4.77 respectively. The time use for each component of unpaid household work is also included in Table 7.8. The average hourly wage rate for farming (D5.93) represents the average hourly pay rate for farm work and gardening (the same in this instance) and that of income-generating activities (D15.45) was the hourly pay rate for market trading. The cooking time (2.7 hours) includes the time for cooking itself (2.4 hours), preparing food (0.1 hours) and washing dishes (0.2 hours), which were assumed closer to cooking than any other sub-component. In the same vein, shopping at the local shop (0.1 hours) was categorised under any "other household work" (0.3 hours), giving an average of 0.3 hours. The wage rate paid for a cook (D5.51) was the average for a school cook (D7.37) and health facility cook (D3.65). The hourly wage rate for a laundress (D5.43) comprised the average of the hourly pay of a health facility laundress (D2.52) and a privately hired one (D8.33). The average hourly pay rate for 'other household work' is based on the overall hourly average rate for female work (D5.75). The hourly wage rates for the remaining sub-components are shown in Table 7.8. The total values generated using the four methods are also presented in the table (Table 7.8). The highest (D62) was obtained using the opportunity cost approach when the average wage rate for women was used, and the replacement cost approach where the hourly wages of the various specialists were used. The lowest values were generated using the human capital approach (when household work is excluded) and the frictional cost method, which considers unpaid work to be zero.

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	Time use (hours)	Hourly household wage rate (D)	Value of farming (D)	Value of income-generating work (D)	Value of household work (D)	Total value of unpaid work (D)	Average hourly wage rate (D)
f female	NR	5.75	30.48	1.15	29.90	62	**5.79**
f male	NR	3.86	20.46	0.77	20.07	41	**3.83**
f :	NR	4.81	25.49	0.96	25.01	51	**4.77**
wages							
	NR	5.16	27.35	1.03	26.83	55	**5.14**
npaid	NR	-	-	-	-	-	
	5.3	5.93	31.43	-	-	31	
	0.2	15.45	3.09	-	-	3	
	-	-	-	-	-	-	
	2.7	5.51	-	-	14.88	15	
	0.3	5.43	-	-	1.63	2	
	0.3	5.00	-	-	1.50	2	
	0.4	2.52	-	-	1.01	1	
od	0.1	6.00	-	-	0.60	1	
	0.8	5.00	-	-	4.00	4	
	0.3	8.40	-	-	2.52	3	
d work	0.3	5.75	-	-	1.73	2	
	5.2	-	-	-	-	30	
						64	**5.98**
tes	NR	4.80	25.46	0.96	0.00	26	**2.43**
tes	NR	0.00	0.00	0.00	0.00	0.00	**0.00**

The opportunity cost approach is used in subsequent analyses in this chapter to estimate indirect costs of the IPTp intervention and those for the treatment cost of LBW babies and anaemic mothers (Section 5.11 for details). The values obtained for the rest of the other three methods are used as part of the sensitivity analysis in Section 9.3 Chapter 9.

7.5. TIME USE FOR IPTp IMPLEMENTATION

The aim of this section is to use the results presented in Section 7.4.3 (using the opportunity cost approach of estimating unpaid household work) to calculate the indirect costs of the IPTp intervention as well as the indirect costs of outpatient and inpatient hospital treatments for LBW and anaemia. The indirect costs of referring LBW and anaemia cases from peripheral facilities to AFPRCH and then to RVTH are also estimated.

7.5.1. Travel time and mode of travel

From the 622 women (70.4%) who travelled to antenatal health facilities, the mean duration of travel one way was 0.75 hours (45 minutes), with the minimum and maximum travel times being 0.17 hours (10 minutes) and 4.5 hours (270 minutes) respectively. Assuming that these women returned home using the same mode of travel, the majority who attended antenatal health facilities spent one and a half hours (1.5 hours) travelling. The majority of the women who attended antenatal health facilities, walked (91.6 %).

7.5.2. Waiting time

On arrival at the health facility, women often spent a long time waiting to see health staff. In eliciting answers on waiting time, two approaches were used. One method asked the women to state their waiting time using the conventional 24-hour clock and the other approach used the rice cooking time as a proxy for waiting time. The latter approach was particularly useful for many rural women who are not literate and would therefore find it virtually impossible to state time in the conventional hours and minutes. As rice is the staple food in The Gambia, it is a matter of fact that all the women in the study area (i.e. village and town) know how to cook it.

Of the 884 women in the sample, 69.8% (n=617) indicated their waiting time. The average time reported spent waiting to see a health professional was 1.78 hours (107 minutes). The minimum and maximum waiting times were 0.08 hours (five minutes) and six hours (360 minutes) respectively. By using the rice cooking approach, out of 880 women who answered the question, the majority (59.5%) waited at the facility for the time it takes to cook rice once, only 1% waited for the time it takes to cook rice four times and 12% did not wait at all (Table 7.9).

Table 7.9 Waiting time approximated to rice cooking

Rice cooking	Frequency	Percentage
No wait	108	12.2
Cook rice 1	526	59.5
Cook rice 2	191	21.6
Cook rice 3	43	4.9
Cook rice 4	9	1.0
Don't know	3	0.3
Total	880	99.5
Missing	4	0.5
Total	**884**	**100.0**

Source: Clinic questionnaire.

A survey of 50 women in the study site observing their rice cooking times revealed that the average time per rice cooking was 1.23 hours (74 minutes), with minimum and maximum times being 0.88 hours (53 minutes) and 1.57 hours (94 minutes) respectively. When this was translated into conventional time, it gave an average waiting time of 1.51 hours (90.5 minutes) per woman, with the minimum and maximum waiting times being zero hours and 4.9 hours respectively. The difference between the conventional 24-hour clock and rice cooking methods of measuring waiting time at the health facility was 15.6 minutes. A paired test of the results showed that the difference between the two results is significant ($p=0.00$) at 95% confidence interval. However, it is not possible to tell which of the two methods is correct. In the case of this study, the conventional time was used in estimating IPTp intervention for easy comparison with other malaria studies that used the same method. However, the significant difference between the methods is noted.

When women were asked to rate their waiting time, 9.4% ($n = 880$) rated it 'very short', 38.2% considered it 'long' and only 5.4% felt it was 'very long'. On their level of satisfaction with the waiting time, 52.1% said they were 'satisfied', 25.4% were dissatisfied, while 9.3% were 'very satisfied' compared to 1.9% who were 'very dissatisfied'.

7.5.3 Opportunity cost of antenatal care time

It was reported in Section 7.3.4 of this chapter that there are many other competing time use needs that have an effect on the health seeking behaviour of antenatal women. When asked what they could have been doing if they were not attending antenatal clinic on that day, most of the women indicated household work (89.9%), followed by farming (2.3%), paid work (1.8%), trading (1.6%) and other (0.2%). Only 0.1% said attending school and the rest indicated nothing. For those engaged in trading and paid work (3.4%), the average earning per day was D170 with the mode being D20 per day.

In order to estimate costs related to escorts, women were asked to indicate whether they were accompanied to antenatal clinics or not. Out of 880 women, the majority (97.5%) were not accompanied. Antenatal health facilities in rural Gambia are utilised by women who often walked together from the same village. Therefore, except for those at the latter stages of their pregnancies or those who fell sick, women are unlikely to be accompanied. The very few, 1.5% (n=13) who were accompanied said they were new to the area and did not know the health facility procedure. One woman was accompanied because she had to use a horse cart, which is normally ridden by men. Apart from these few cases, the rest went to the health facilities in the company of small children or their peers. To assess how much more time women would lose for the rest of the clinic day, they were questioned whether they would return home immediately after the antenatal visit. The majority (92.9%) said they were going home straight away.

7.5.4. Indirect cost of IPTp intervention

As already explained in Section 6.3.1 of Chapter 6, six minutes was required for the IPTp contact time during the first antenatal health facility visit, and three minutes each for the subsequent three visits. Therefore, the total time required for IPTp contact was 0.25 hours (15 minutes for the four visits). Travelling time for a return trip to an antenatal health facility was 1.5 hour (90 minutes). However, the number of visits required for IPTp (n = 4) against the national antenatal visit rate of 3.4 visits, means an extra 0.6 visits for the IPTp alone. Therefore, the travelling time for IPTp was 0.75 hours (45 minutes). The average waiting time per woman at an antenatal health facility was 1.78 hours (107 minutes) using the conventional 24-hour clock method (Section 7.5.2). The total time required for IPTp was the sum of the contact time for IPTp (0.25 hours), the extra travelling time required (0.75 hours) and the waiting time of 0.89 hours, giving the total time of 1.89 hours as indicated in Table 7.10.

Table 7.10 Time use for IPTp at the antenatal health facility

Activities	Time (hours)
Travelling	0.75
Waiting	0.89
First contact	0.1
Second to fourth contact	0.15
Total IPTp	**1.89**

Source: Hospital observation study.

The average hourly pay rate generated using the female wage rate (D5.79) calculated using the opportunity cost approach gave the unit indirect costs shown in Table 7.11. The unit cost for waiting was D5.15 and for contact was D1.45. The sum of these two and that for travel gave the total unit cost of IPTp as D10.94. Therefore, the total indirect cost of IPTp for the 55,678 women in the study area was D609,117 for Base case I and D134,004 for Base case II.

Table 7.11 Indirect cost of IPTp intervention

Health facility	Multi-gravidae	Hourly pay rate (D)	Travel cost (D)	Waiting cost (D)	Contact cost (D)	IPTp cost (D)	Total IPTp
Base case I	**55,678**	5.79	4.34	5.15	1.45	10.94	**609,117**
Base case II	**12,249**	5.79	4.34	5.15	1.45	10.94	**134,004**

Source: Source: Hospital observation study

7.6. INDIRECT COSTS OF LOW BIRTH WEIGHT AND ANAEMIA TREATMENT

The aim of this section is to present the results of the indirect costs for treating LBW babies, and moderately and severely anaemic mothers. It specifically takes into consideration the travel time to and from the hospital in the case of outpatient treatment for anaemic mothers and the waiting and contact time during hospital visits. Also included is the time taken by any caregiver (escort) accompanying the patient for the duration of care. The section also looks at the indirect costs of any admission for the two conditions at AFPRCH and any referral and subsequent admission at the RVTH.

7.6.1. Indirect cost of outpatient treatment of anaemia at AFRPCH

Table 7.12 presents the results of the hospital observation study of anaemia cases treated at AFPRCH in Farafenni and RVTH in Banjul. In the case of moderate or severe anaemia, treatment is possible at the outpatient department of AFPRCH in Farafenni.

It has been stated earlier in this chapter that a visit to antenatal health facilities takes about 1.5 hours for a round trip (see Section 7.5.1) but the travel time to and from hospitals takes approximately four times more than it takes for a return trip to basic health facilities. The reason is that The Gambia is served by only four public hospitals (including AFPRCH and RVTH). This makes access to such tertiary health facilities more time consuming for patients than going to basic health facilities. In this study, all patients observed at the two hospitals were accompanied by at least one woman.

The four hospital outpatient visits required an average of six hours of travel per trip per patient and 24 hours for the four trips. The average waiting time per patient per hospital visit was 1.85 hours (111 minutes) with the lowest and highest times being 1.12 hours (67 minutes) and 2.8 hours (168 minutes) respectively. The maximum times were attributed to periods of no electricity when women had to wait for a long time before getting results of blood tests. The average contact time with health staff was estimated at only 0.166 hours (10 minutes) per patient per trip with the total for the four trips being 0.66. The average time required for the four OPD visits was 32.06 hours (i.e. 24 hours on travel, 7.4 hours waiting and 0.66 contact times).

Table 7.12 Time use for treating anaemia

	AFPRCH	RVTH
OUTPATIENT DEPARTMENT		
Moderate/Severe Anaemia	Unit	Unit
Travelling	6 hours (2 ways)	N/A
Number of visits	4 visits	
Duration per visit		
Waiting	1.85 hours	N/A
Contact	0.166 hours	N/A
Total time use	2.01 hours	None
Number of escorts	One woman	N/A
INPATIENT (ADMISSIONS)		
Very Severe Anaemia		
Average length of stay (non-fatal)	7 days	7 days
Average length of stay (fatal)	4 days	4 days
Number of Escorts	One woman	One woman
Daily visitors:		
One woman	2 hours (4 - 6pm)	2 hours (4 – 6pm)
One man	0.166 hours	0.166 hours

Source: Hospital observation study and secondary data from AFPRCH and RVTH

Using the hourly rate of pay of D5.79 estimated from the first valuation method of unpaid work (see Section 7.4.3) and multiplying it by contact, waiting and return travel times to hospital, gave a unit cost of D186. This represents the indirect cost for one anaemic mother treated at AFPRCH. Since all the patients were accompanied, the unit cost of D186 per patient was multiplied by two in order to accommodate the indirect cost incurred by the escort. Assuming the escort was a female, the same wage rate was used. As indicated in Table 7.13, the total indirect costs for a patient and one escort was D372.

Table 7.13 Indirect cost of outpatient treatment for moderate/severe anaemia

Cost determinants					Hourly pay (D)	Travel cost (D)	Waiting cost 1-4 (D)	Contact cost (D)	Total unit cost (D)
	Number of visits	Travel time (hours)	Waiting (hours)	Contact (hours)					
Patient	4	6.0	1.85	0.166	5.79	138.96	42.85	3.84	186
Escort	4	6.0	1.85	0.166	5.79	138.96	42.85	3.84	186
Total									**372**

Source: Hospital observation study and secondary data from AFPRCH.

7.6.2. Indirect cost of inpatient treatment of anaemia at AFPRCH

In addition to outpatient treatment of anaemia, AFPRCH has the necessary facilities to treat some anaemic patients in-house. By using the hourly wage rate (D5.79) obtained from the opportunity cost approach of valuing unpaid work, the indirect cost of an anaemic mother admitted at AFPRCH for seven days was D434, the whole of which was incurred from the hospital inpatient time. The combined indirect cost per admission (including that of the escort) was D868. Through the observation study, it was discovered that every admitted anaemic mother had an escort, usually a close relative who stayed with her at the hospital for the entire duration of her hospital stay.

In addition to their own time and that of their escorts, each patient had a female family visitor on a daily basis who stayed for an average period of two hours per day and a male visitor for only 0.166 hours (10 minutes) per day for the average of seven days she was admitted (hospital observation study). The official visiting time for all the public hospitals in The Gambia (AFPRCH and RVTH inclusive) is from 4-6 pm daily, except for weekends when the time is extended by one hour from 4-7pm. Unlike males, who rarely stay for more than an average of 10 minutes, females tend to utilise the full visiting time each day. It is a daily occurrence for them to be asked to leave the hospital when the visiting hours are over.

The indirect cost per female visitor was D111 and the corresponding cost for a male visitor was only D25. The average indirect cost per admission of an anaemic mother at AFPRCH was D1,004. The details of the indirect costs of patients, their escorts and visitors are given in Table 7.14. The indirect cost for a fatal anaemia case that stayed in the hospital for four days was D573. All these costs are incorporated in the estimation of treatment costs for LBW and anaemia at the hospital.

Table 7.14 Unit indirect costs of inpatient care for anaemia at AFPRCH

	Average Length of Stay (ALoS) (Days)	Travel time (hours)	Average time per day spent at the hospital (hours)	Hourly pay (D)	Travel cost (D)	Inpatient (IP) cost (D)	Total inpatient cost (D)
Non-fatal case							
Patient	7	0.0	10.7	5.79	0.00	433.67	434
Escort	7	0.0	10.7	5.79	0.00	433.67	434
Female visitor	7	0.75	2.0	5.79	30.40	81.06	111
Male visitor	7	0.75	0.166	3.83	20.11	4.45	25
Total					**51**	**953**	**1,004**
Fatal case							
Patient	4	0.0	10.7	5.79	0.00	247.81	248
Escort	4	0.0	10.7	5.79	0.00	247.81	248
Female visitor	4	0.75	2.0	5.79	17.37	46.32	64
Male visitor	4	0.75	0.166	3.83	11.49	2.54	14
Total					**29**	**544**	**573**

Source: Hospital observation study and secondary data from AFPRCH.

7.6.3. Indirect cost of referrals of LBW babies and/or severe anaemia cases

Referral for VLBW and ELBW is in two stages; from peripheral health facilities to AFPRCH and from AFPRCH to RVTH. Most of the very severe anaemia cases have one stage of referral (to AFPRCH only) but some rare cases have two (i.e. for those who had to be referred to RVTH). The main referral hospital in The Gambia is RVTH. Any illnesses that cannot be treated at rural hospitals, such as AFPRCH, are referred there for further investigation and treatment. In cases of very severe anaemia, VLBW and ELBW cases that are not usually treated at AFPRCH, immediate referral is made from health centres to AFPRCH and then to RVTH. The average time for the first referral to AFPRCH was 0.88 hours and that for a referral to RVTH in Banjul (including ferry crossing) was three hours. This information has been further verified by the candidate after following an ambulance for a single leg of a referral from Farafenni to Banjul.

Table 7.15 presents the results of the hospital observation study of LBW babies referred from peripheral health facilities to AFPRCH and on to RVTH. The average time use on the part of a patient and his/her escort for the first referral was 0.88 hours each and for the two was six hours (three hours each) for the second referral. Therefore, the indirect cost of the first referral of a VLBW and ELBW, and/or anaemic mother, are as indicated in Table 7.16; D5.10 for the patient alone and twice that amount (D10.20) for the patient and the escort. The corresponding amount for the second referral was D34.74 (i.e. D17.37 each). The indirect cost of the few minutes spent at the A & E departments of the hospitals during referral is considered too negligible to include.

Table 7.15 Time use for treating low birth weight (LBW)

	AFPRCH	RVTH
OUTPATIENT DEPARTMENT		
Low Birth Weight (LBW)	N/A	N/A
Referral		
First referral (LBW)	0.88 hours	3 hours
Second referrals (LBW)	0.88 hours	3 hours
INPATIENT (ADMISSIONS)		
Very Low Birth Weight (LBW)		
Average length of stay (non-fatal)	-	21 days
Average length of stay (fatal)	-	7 days
No. of Escorts	-	One woman
Daily visitors:		
One woman	-	2 hours
One man	-	0.166 hours
Extremely LBW		
Average length of stay (non-fatal)	-	28 days
Average length of stay (fatal)	-	5 days
No. of Escorts	-	1 woman
Daily visitors:		
One woman	-	2 hours
One man	-	0.166 hours

Source: Hospital observation study and secondary data from AFPRCH and RVTH

Table 7.16 Unit indirect costs of referral from AFPRCH to RVTH

Cost determinants			Hourly pay (D)	Referral cost (D)
	Number of Referrals	Referral time (hours)		
First referral				
Patient	1	0.88	5.79	5.10
Escort	1	0.88	5.79	5.10
Sub-total				**10.20**
Second referral				
Patient	1	3	5.79	17.37
Escort	1	3	5.79	17.37
Sub-total				**34.74**

Source: Hospital observation study

7.6.4. Indirect cost of inpatient treatment of VLBW and ELBW babies at RVTH

The category of LBW babies being considered in this study (less than or equal to 1.5kg) are not usually cared for at the outpatient department in The Gambia for reasons already given in Section 5.10.3.5, Chapter 5. While the women are often advised to use the 'kangaroo' method to care for the less severe cases (i.e. greater than 1.5kgs and less than or equal to 2.5 kgs), severe cases are usually admitted, mainly at the RVTH. The kangaroo method, according to WHO, is a non-conventional method of caring for LBW babies after initial stabilisation (WHO, 1997). It requires a continuous use of body heat (i.e. skin-to-skin contact) to keep the baby warm and to ensure exclusive breastfeeding. The method is often used as an alternative to incubator care for LBW babies, especially in environments where hospitals do not have such equipment or the apparatus are in limited supply (WHO, 1997). Although essential in overall care delivery, it was not within the scope of this study to investigate home care.

The average length of stay in the paediatrics wards at the RVTH is 15 days. However, from the findings of the study conducted at the RVTH, complemented by the results of searching hospital records and interviews with key staff of the ward, it was found that non-fatal VLBW and ELBW babies admitted stayed for an average of 21 and 28 days respectively. It was also observed that, in addition to the mother of the child, an escort per patient stayed for the entire duration of the admission of the baby. The number and types of visitors, as well as the duration of visits, were not different from those recorded at AFPRCH in the case of hospitalisation of anaemic mothers, i.e. two hours per day for women and 0.166 hours for men (see Section 7.6.2). The details of indirect costs for VLBW and ELBW are presented in Table 7.17. The unit indirect cost for VLBW was D1,301 and for ELBW was D1,735.

By including the costs incurred by the escorts and daily female and male family visitors, the total costs for VLBW and ELBW rose to D3,011 and D4,013 respectively. The corresponding indirect costs for fatal cases at the hospital were D1,004 for seven days and D717 for five days.

Table 7.17 Unit indirect costs of inpatient care for LBW and ELBW at the RVTH

	Average length of stay (days)	Travel time (hours)	Average time per day spent at the hospital (hours)	Hourly pay (D)	Travel cost (D)	Inpatient cost (D)	Total inpatient cost (D)
A. Non-fatal cases							
LBW							
Patient	21	0.0	10.7	5.79	0.00	1,301.01	1,301
Escort	21	0.0	10.7	5.79	0.00	1,301.01	1,301
Female	21	0.75	2.0	5.79	91.19	243.18	334
Male	21	0.75	0.166	3.83	60.32	13.35	74
Total VLBW					**152**	**2859**	**3,011**
ELBW							
Patient	28	0.0	10.7	5.79	0.00	1,722.46	1,735
Escort	28	0.0	10.7	5.79	0.00	1,722.46	1,735
Female	28	0.75	2.0	5.79	121.59	321.96	446
Male	28	0.75	0.166	3.83	80.43	17.93	98
Total ELBW					**202**	**3785**	**4,013**
B. Fatal cases							
LBW							
Patient	7	0.0	10.7	5.79	0.00	430.61	434
Escort	7	0.0	10.7	5.79	0.00	430.61	434
Female	7	0.75	2.0	5.79	30.40	80.49	111
Male	7	0.75	0.166	3.83	20.11	4.48	25
Total VLBW					51	946	1,004
ELBW							
Patient	5	0.0	10.7	5.79	0.00	307.58	310
Escort	5	0.0	10.7	5.79	0.00	307.58	310
Female	5	0.75	2.0	5.79	21.71	57.49	80
Male	5	0.75	0.166	3.83	14.36	3.20	18
Total ELBW					**36**	**681**	**717**

Source: Hospital observation study and secondary data from RVTH

7.6.5. Indirect cost of inpatient treatment of anaemia at the RVTH

The average length of stay for an anaemia patient as well as the number and types of visitors to these patients admitted at RVTH were the same as those reported for AFPRCH (Tables 7.14), i.e. an average of two hours per female and 0.166 hours (10 minutes) per male for seven days. Therefore, the total indirect cost for a non-fatal patient, her escort and daily visitors was also D1,004. The corresponding cost for a fatal case was D573 as shown in Table 7.18.

Table 7.18 Unit indirect costs of inpatient (IP) care for anaemia at the RVTH

	Average length of stay (Days)	Travel time (hours)	Lost time per day (hours)	Hourly pay (D)	Travel cost (D)	Inpatient cost (D)	Total inpatient cost (D)
A. Non-Fatal case							
Patient	7	0.0	10.7	5.79	0.00	433.67	434
Escort	7	0.0	10.7	5.79	0.00	433.67	434
Female visitor	7	0.75	2.0	5.79	30.40	81.06	111
Male visitor	7	0.75	0.166	3.83	20.11	4.45	25
Total					**51**	**953**	**1,004**
B. Fatal case							
Patient	4	0.0	10.7	5.79	0.00	247.81	248
Escort	4	0.0	10.7	5.79	0.00	247.81	248
Female visitor	4	0.75	2.0	5.79	17.37	46.32	64
Male visitor	4	0.75	0.166	3.83	11.37	2.54	14
Total					**29**	**544**	**573**

Source: Hospital observation study and secondary data from RVTH.

7.7. SUMMARY

The data presented in this chapter revealed that household work in rural Gambia varies only slightly by location and health division. However, the differences became more apparent when the same data were analysed by day of the week or season of the year. It was revealed that farming is predominantly practised in rural villages, while women in the rural towns spent more time on household work. In terms of days of the week, religion and culture play important roles in work patterns. For example, because of Friday prayers, women do not normally undertake farm work on that day, and for cultural reasons, Wednesdays are regarded as rest days from farm work by most communities. The results also reveal that women spent significant amounts of time waiting before accessing care, especially in hospitals. In terms of indirect costs, it was shown that LBW and anaemia could cost a lot of resources not only to those affected but also to their escorts and relatives as well. The indirect unit costs of treatment for LBW and anaemia were found to be far more than that of the IPTp intervention.

Specifically, the indirect unit cost of IPTp was D10.94, while indirect unit costs of treatment were D372 for outpatient treatment of anaemia, D1,004 for inpatient treatment of anaemia at AFPRCH, and D34.74 for referral of LBW/anaemia cases from AFPRCH to RVTH. The respective indirect costs of inpatient care for non-fatal VLBW and ELBW at RVTH were D3,011 and D4,013, with corresponding costs for fatal cases being D1,004 and D717. Finally, D1,004 was the inpatient care cost of non-fatal anaemia cases admitted at the RVTH and the corresponding cost for a fatal case was D573. The variation in average hourly wage rate dependent on the method of valuation used is likely to mean that the size of indirect costs will depend greatly on the estimation method used. The influence of the method of valuing indirect costs on incremental cost-effectiveness ratios is explored in the sensitivity analysis (Chapter 9).

CHAPTER 8: RESULTS III: EFFECTIVENESS AND CONSEQUENCES OF IPTp

8.1 INTRODUCTION

This chapter presents the effectiveness of the IPTp intervention in terms of cases of Low birth weight (LBW) ((Very Low birth weigh (VLBW) and Extremely Low birth weight (ELBW)) and anaemia (moderate, severe and very severe) averted, deaths from LBW and anaemia averted, and DALYs averted. The resource use consequences of IPTp in savings to the health care provider as well as to patients and their families are also estimated. With the introduction of IPTp in The Gambia, it is hoped that, if effective, it will prevent LBW in newborn babies and anaemia in mothers. A lower incidence of LBW and anaemia and of care-seeking for these conditions will free up scarce provider and patient resources for other urgent needs.

There are two main sections to this chapter; health consequences and resource-savings. Section 8.2 presents the effectiveness results of the IPTp in terms of cases averted, deaths averted and DALYs averted of LBW and the three types of anaemia. This was done in two phases, Base cases I and II. Base case I uses the multigravidae population in the study site and Base case II uses the multigravidae population in the study site who do not sleep under bednets (either insecticide-treated or untreated). The resource use consequences of the IPTp intervention for Base cases I and II are the subject of Section 8.3. Finally, Section 8.4 summarises the key findings of the chapter.

8.2 HEALTH CONSEQUENCES OF THE INTERVENTION

The purpose of the IPTp trial was to curb the morbidity and mortality effects of LBW for infants of multigravidae and/or anaemia for mothers in rural Gambia. Therefore, the results were reported in relation to the prevalence of peripheral parasitaemia, birth weight and anaemia. Although all these three have been considered by the trial, the focus of the study reported here is on those resource-consuming conditions such as VLBW, ELBW, moderate and severe anaemia. This is because prevalence of parasitaemia may not necessarily lead to illnesses that require resource use (Amadou Mbaye, personal communication). The effectiveness data came from results of the trial itself. These data were extrapolated using the updated version of the 2001 multigravidae figure reported in Chapter 6, Section 6.3.1.

8.2.1. Trial results

The IPTp effectiveness results are presented in terms of cases of and deaths from LBW and anaemia averted due to the trial. Issues around confounding factors are outlined in the same section.

8.2.1.1. Effectiveness of IPTp on LBW

The effectiveness results of IPTp on LBW were presented in the form of mean birth weight for IPTp and control groups (Table 8.1). Further analysis of the data was conducted in order to adjust it into the three types of LBW required for this study. The proportion of LBW babies (<2500 g) for the main trial sample as a whole was 5.4% for IPTp and 7.1% for control. There was no statistically significant difference between the IPTp and control in terms of mean birth weight (p=0.16) (Table 8.1). For women who slept under a bednet 'always' and 'sometimes', no significant difference between mean birth weights for the IPTp and control groups was found at the 95% confidence interval (p=0.87). However, there was a statistically significant difference in mean birth weight for those women who did not use bednets for IPTp and control (p-value =0.002) (Mbaye et al 2006).

A sub-group analysis conducted on the non-bednet user multigravidae (22%) in the study area produced prevalence rates of 4.3% LBW (<2500g) for IPTp and 7.4% for control (see Table 8.3 later). The distribution of birth weights into various categories were, for IPTp, 4.3% LBW, 0.5% VLBW and 0% ELBW, and the corresponding values for control were 7.4%, 0.3% and 0%.

Table 8.1 Mean birth weight (and prevalence of LBW) by bednet use and number of bednet treatments

	N	IPTp	Control	Difference	P
All Women	55,678 (100%)	3103g (5.4%)	3075g (7.1%)	28g	0.156
Bednet Usage					
Always	40,840 (73%)	3091g	3088g	3g	0.872
Sometimes	2,980 (5%)	3136g	3123g	13g	0.874
Never	11,858 (22%)	3147g (4.3%)	3004g (7.4%)	143g	0.002
Number of treatments					
One	8,890 (16%)	3078g	3079g	1g	0.977
Two	13,111 (24%)	3093g	3036g	57g	0.167
Three	16,768 (30%)	3138g	3115g	23g	0.512
Four	16,909 (30%)	3094g	3058g	36g	0.288

Source: Extrapolated from the main effectiveness trial data.

8.2.1.2. Effectiveness of IPTp on anaemia

The prevalence rate for anaemia as a whole was 11% for IPTp and 9% for control, as indicated in Table 8.2. These results showed that there was no statistically significant difference between IPTp and control at 95% confidence interval (p-value of 0.17).

Table 8.2 Prevalence of anaemia by bednet use and number of treatment (percentage with anaemia in parenthesis)

	N	IPTp	Control	P
All Women	**55,678**	**2,968/28,011 (11%)**	**2,412/27,401 (9%)**	**0.17**
Bednet Usage				
Always	40,391(73%)	1,829/19,080 (10%)	1,325/18,312 (7%)	0.11
Sometimes	2,891(5%)	212/1,431 (15%)	27/1,246 (2%)	NA
Never	12,395 (22%)	742/5,645 (13%)	928/5,804 (16%)	0.40
Number of treatments				
One	9,667(17%)	636/5,168 (12%)	451/4,426 (10%)	0.52
Two	13,405 (24%)	769/7,023 (11%)	557/6,281 (9%)	0.44
Three	16,236 (29%)	795/7,553 (11%)	928/8,560 (11%)	0.90
Four	16,370 (29%)	769/8,136 (9%)	477/8,109 (6%)	0.10

Source: Extrapolated from the main effectiveness trial data.

A sub-group analysis of non-bednet users produced an anaemia prevalence rate of 13% for IPTp and 16% for control (Table 8.3). However the result was found to be less significant at 95% confidence interval (p-value = 0.40). The distribution of haemoglobin (Hb) concentrations into three types — mild, moderate and severe anaemia, as presented in Table 8.3 — shows that mild anaemia forms the largest group with 89.4% for IPTp and 91.2% for control, and the smallest was severe anaemia with 1.9% and 1.2% for control. Moderate anaemia lies between the two with 8.7% and 7.6% for IPTp and control respectively.

Table 8.3 Distribution of LBW and anaemia in rural Gambia

		Categories		
	Full sample	**ELBW <1000g**	**VLBW 1000g–1499g**	**LBW 1500g–2500g**
LBW				
IPTp	4.3%	0%	0.5%	99.5%
Control	7.4%	0%	0.3%	99.7%
Anaemia				
		Severe, <5g/dl	**Moderate, 5g/dl–7g/dl**	**Mild, 7g/dl–11g/dl**
IPTp (IPTp)	11	1.9%	8.7%	89.4%
Control	9%	1.2%	7.6%	91.2%

Source: Main effectiveness trial result.

8.2.1.3. Discussion on confounding factors

The results of the trial revealed that, overall, IPTp with SP is not effective for multigravidae in The Gambia. A number of possible reasons were advanced for this. A previous study in The Gambia (Greenwood et al, 1989) in which pregnant women were given regular chemoprophylaxis with Maloprim found a reduction in the prevalence of LBW and anaemia in primigravidae but no significant effects on birth weight or anaemia in multigravidae, despite a reduction in parasitaemia (Mbaye at al, 2006). With the median attendance in the trial of three doses of SP for IPTp and of placebo for control, the compliance rate was above the WHO-recommended doses of at least two (Chapter 1). This good compliance is due to high antenatal attendance in The Gambia.

As at 2003, the percentage of women aged 15-49 who attended antenatal clinics at least once during pregnancy, and were seen by skilled health personnel (i.e. doctors, nurses or nurse midwives) was 91% (WHO, 1999). High compliance is likely to benefit HIV positive women on IPTp more than those on control, but in the case of The Gambia where the adult HIV prevalence rate is comparatively low (see Chapter 4, Section 4.6), this issue is not relevant.

One important activity likely to have an effect on the outcomes of the trial was the weekly follow-up by fieldworkers during the entire trial period. During such follow-ups, women suspected of having severe anaemia at any point during the trial had their blood taken for Hb and parasitaemia tests and were referred to the hospital. Those women who developed a clinical attack of malaria (fever accompanied with a positive parasitaemia) during the study were treated with chloroquine in line with Gambia Standard Drug Treatment Guidelines, with careful patient follow-up and treatment with quinine if there was no improvement within 48 hours (MRC/Gambia, 2002).

Furthermore, at each clinic visit, women were asked about side effects or complications of the study medication. Those with possible sulpha drug reaction had their blood taken for Hb and parasitaemia tests; and were completely withdrawn from the trial and did not receive any further SP (MRC, 2002) medication. This eventually left the trial with women who were free from any illnesses. Given that the LBW and anaemia status were measured after delivery, most of those women who might have been affected could have been withdrawn from the trial before their delivery time. The main difference between the trial and routine antenatal care in The Gambia is that the rigid follow-up, which was an integral part of the trial, is non-existent in practice. The implication of this is that the number of LBW and anaemia cases will be understated.

8.2.2. Health outcome measures

The health consequences of the IPTp intervention are presented using the health outcomes of the trial under two scenarios or base cases. The first, Base case I, uses the effectiveness rates presented for the main trial, and the second, Base case II, uses the effectiveness rates for those not sleeping under bednets. This is because the effectiveness rate of IPTp for those women who use bednets and those who do not is different. The outcome measures in each case are presented in terms of cases and deaths averted from LBW, and anaemia, and in terms of DALYs averted for the two conditions. The details of these outcome measures are shown in Table 8.4. Contrasting effectiveness data from sources outside the trial are tested in sensitivity analysis (Section 9.3).

8.2.3. Results: Base case I

This sub-section presents the results of IPTp for Base case I in terms of cases of and deaths averted for both LBW and anaemia. In addition, DALYs averted were estimated and presented for the same Base case.

8.2.3.1. Low Birth Weight

The number of LBW cases was 3,953 in the control arm and 3,007 in the IPTp arm, leading to 946 cases averted. The cases of VLBW for the control were 12, compared to 15 for IPTp. Of these, 10 and 13 cases, respectively, were successfully treated, leading to -3 cases averted. Two deaths in each trial arm occurred at the AFPRCH, leading to zero deaths averted. There were no cases of ELBW in either arm of the trial, which means the cases averted of ELBW were automatically equivalent to zero (see Table 8.4).

Table 8.4 Effectiveness of IPTp on LBW for all multigravidae: Base case I

Base case I: Multigravidae population	**Frequency**		
	Control	**IPTp**	**Cases/ Deaths averted**
Prevalence of LBW (all types)	**3,953**	**3,007**	**946**
Low birth weight	3,941	2,992	949
Very low birth weight	12	15	-3
Extremely low birth weight	0	0	0
Royal Victoria Teaching Hospital (RVTH)			
Very low birth weight (fatal) (12.5%)	2	2	0
Very low birth weight (non-fatal)	10	13	-3
Extremely low birth weight (fatal)	0	0	0
Extremely low birth weight (non-fatal)	0	0	0

Source: Main effectiveness trial and secondary data.

8.2.3.2. Anaemia

The number of anaemia cases in the control arm was 5,011, compared to 6,125 for IPTp. The overall number of cases of all types of anaemia averted was -1,114. The cases of very severe anaemia were broken down as 45 for control and 87 for IPTp, giving -42 cases of very severe anaemia averted. The corresponding figures for moderate and severe anaemia cases averted were -152 and -14 respectively. The rest of the cases averted (-906) fell into the mild anaemia category. The cases of moderate anaemia treated at the hospital outpatient level numbered 38 for the control and 53 for IPTp, leading to -15 cases averted. The cases of severe anaemia treated at the AFPRCH outpatient department were five for the control and nine for IPTp, leading to -4 cases averted. Of the non-fatal very severe anaemia cases treated at the AFPRCH, 38 were from the control and 73 from IPTp, leading to -35 cases averted. The corresponding cases averted from those treated at the RVTH were only two, with more cases in the intervention than control. Therefore, the total number of non-fatal cases averted of very severe anaemia, treated at hospital was -37. In terms of deaths, five occurred on the control arm and 10 on the IPTp arm, resulting in -5 deaths averted. These details are given in Table 8.5.

Table 8.5 Effectiveness of IPTp on anaemia for all multigravidae: Base case I

	Frequency		
	Control	**IPTp**	**Cases/Deaths averted**
Prevalence of anaemia (all types)	**5,011**	**6,125**	**-1,114**
Mild anaemia	4,570	5,476	-906
Moderate anaemia	381	533	-152
Severe anaemia	15	29	-14
Very severe anaemia	45	87	-42
AFPRCH			
Moderate anaemia	38	53	-15
Severe anaemia	5	9	-4
Very severe anaemia (fatal) (11.8%)	5	10	-5
Very severe anaemia (non-fatal)	38	73	-35
Referrals to RVTH			
Very severe anaemia (fatal) (2.5%)	0	0	0
Very severe anaemia (non-fatal)	2	4	-2

Source: Main effectiveness trial and secondary data

8.2.3.3. Disability-adjusted life years (DALYs)

DALYs averted because of IPTp varied from zero to -0.69 depending on the condition. The zero represents DALYs averted due to ELBW and the -0.69 due to VLBW. The total DALYs averted from LBW alone was -0.69. The DALYs averted for moderate, severe and very severe anaemia ranged from zero to -125.15.

The lowest figure represents DALYs averted for severe anaemia and the highest represents DALYs averted for very severe anaemia cases seen at the AFPRCH. The total DALYs for the IPTp intervention was -125.8. The details of the various DALYs are given in Table 8.6.

Table 8.6 Summary of DALY estimated values: Base case I

	Control			IPTp			TOTAL
	YLD	**YLL**	**DALYs**	**YLD**	**YLL**	**DALYs**	**DALYs Averted**
Low Birth Weight							
VLBW	4.80	61.46	57.70	5.49	61.46	58.39	-0.69
ELBW	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Sub-total	**4.80**	**61.46**	**57.70**	**5.49**	**61.46**	**58.39**	**-0.69**
Anaemia							
Moderate anaemia	0.06	0.00	0.06	0.08	0.00	0.08	-0.02
Severe anaemia	0.01	0.00	0.01	0.01	0.00	0.01	0.00
Very severe anaemia AFPRCH	0.55	123.59	123.83	2.32	247.19	248.89	-125.06
Very severe anaemia RVTH	0.06	0.00	0.06	0.13	0.00	0.13	-0.07
Sub-total	**0.68**	**123.59**	**123.96**	**2.54**	**247.19**	**249.11**	**-125.15**
TOTAL							**-125.8**

Source: Estimated from the main effectiveness trial data.

8.2.4. Results: Base case II

This sub-section presents the results of IPTp for Base case II in terms of cases of and deaths averted for both LBW and anaemia. In addition, DALYs averted were estimated for the same Base case.

8.2.4.1. Low Birth Weight

The cases of LBW in Base case II were 906 for the control and 527 for IPTp, resulting in 379 cases averted. All cases averted represent LBW babies, as illustrated in Table 8.7. There were no deaths in either arm of the trial.

Table 8.7 Effectiveness of IPTp on LBW for non-bednet users: Base case II

	Frequency		
	Control	**IPTp**	**Cases/ deaths averted**
Prevalence of LBW (all types)	**906**	**527**	**379**
Low birth weight	903	524	379
Very low birth weight	3	3	0
Extremely low birth weight	0	0	0
Royal Victoria Teaching Hospital (RVTH)			
Very low birth weight (fatal) (12.5%)	0	0	0
Very low birth weight (non-fatal)	3	3	0
Extremely low birth weight (fatal)	0	0	0
Extremely low birth weight (non-fatal)	0	0	0

Source: Main effectiveness trial and secondary data.

8.2.4.2. Anaemia

The cases of anaemia recorded by each arm of the trial were 1,961 for control and 1,592 for IPTp, leading to 369 cases averted. Of these, very severe anaemia accounted for 18 for control and 22 for IPTp, resulting in -4 cases averted. Other cases averted were -2 for severe anaemia and 10 for moderate anaemia, with the rest (365) being mild cases averted. Out of those seen at the hospital, 15 non-fatal cases of very severe anaemia were successfully treated from the control arm and 19 from the IPTp, leading to -4 cases averted. Of the number of moderate and severe cases treated at the outpatient department of AFPRCH, one and zero cases, respectively, were averted. Of the fatal very severe anaemia cases treated at AFPRCH, two each were treated from the control and IPTp arms, leading to zero deaths averted. There was one non-fatal case successfully treated at the RVTH from each arm, leading to zero deaths averted (see Table 8.8).

Table 8.8 Effectiveness of IPTp on anaemia for non-bednet users: Base case II

Prevalence of anaemia (all types)	Control	IPTp	Cases/Deaths averted
	1,961	**1,592**	**369**
Mild anaemia	1,788	1,423	365
Moderate anaemia	149	139	10
Severe anaemia	6	8	-2
Very severe anaemia	18	22	-4
AFPRCH			
Moderate anaemia	15	14	1
Severe anaemia	2	2	0
Very severe anaemia (fatal) (11.8%)	2	2	0
Very severe anaemia (non-fatal)	15	19	-4
Referrals to RVTH			
Very severe anaemia (fatal) (2.5%)	0	0	0
Very severe anaemia (non-fatal)	1	1	0

Source: Main effectiveness trial and secondary data.

8.2.4.3 Disability-adjusted life years (DALYs)

The sum of the DALYs averted for LBW in Base case II was zero. DALYs averted for the three types of anaemia were -0.13 as shown in Table 8.9. The DALYs averted for moderate and severe anaemia was zero each. The -0.13 represents DALYs averted for very severe anaemia. Therefore, the total DALYs averted for Base case II was -0.13. The details of the composition of the DALYs averted are presented in Table 8.9.

Table 8.9 Summary of DALY estimated values: Base case II

	Routine ANC			IPTp			TOTAL
	YLD	**YLL**	**DALYs**	**YLD**	**YLL**	**DALYs**	**DALYs Averted**
Low Birth Weight							
VLBW	1.44	0.00	1.44	1.44	0.00	1.44	0.00
ELBW	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Sub-total	**1.44**	**0.00**	**1.44**	**1.44**	**0.00**	**1.44**	**0.00**
Anaemia							
Moderate anaemia	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Severe anaemia	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Very severe anaemia AFRPC	0.47	49.44	49.79	0.60	49.44	49.92	-0.13
Very severe anaemia RVTH	0.03	0.00	0.03	0.03	0.00	0.03	0.00
Sub-total	**0.50**	**49.44**	**49.82**	**0.63**	**49.44**	**49.95**	**-0.13**
TOTAL							**-0.13**

Source: Estimated from the main effectiveness trial data.

8.3 RESOURCE SAVINGS

Another consequence of the IPTp intervention is the potential resource savings to the health care provider, patients and their families. The consequences to the provider are in the form of treatment cost savings from VLBW, ELBW, and the three types of anaemia (moderate, severe and very severe), and from deaths which would have happened without the IPTp intervention. The consequences to patients are savings in direct and indirect hospital treatment costs of LBW and anaemia not only to themselves but also to their families. Further potential resource savings to patients and their families could arise when the number of deaths from LBW and anaemia are curtailed because of the IPTp.

8.3.1 Results: Base case I

The resource savings realised due to the IPTp intervention for Base case I in terms of savings to the provider, patients, and their families are presented in this sub-section. Since health consequences in the IPTp arm were in general worse than in the control arm, these resource savings were negative, and hence are termed for simplicity 'resource losses' though the negative signs are retained here for consistency with normal practice.

8.3.1.1 Losses to the provider

The resource loss to the provider for the treatment of -3 cases of VLBW averted was -D39,681. The details are given in Table 8.10. This includes the referral transport cost from the peripheral facilities and the cost for the first escort nurse from health centre, 10% of A & E costs at the AFPRCH, referral cost to RVTH for the 340 km journey and the cost for the second referral nurse to RVTH, 10% of A & E costs at the RVTH and 21 days in-patient costs. The corresponding cost to the provider for a fatal VLBW and ELBW case at the hospital within seven days was zero because there were no deaths from either type of LBW. The loss to the provider for the treatment of -15 moderate anaemia cases, -4 severe cases, -37 very severe cases averted and -5 deaths averted (Table 8.10) was -D201,679. The total loss to the provider because of IPTp, which is the sum of losses from treating LBW and anaemia, was -D241,360.

Table 8.10 Summary of resource losses

Resource-savings/Losses	LBW	Anaemia	TOTAL (D)	%	LBW	Anaemia	TOTAL (D)	%
	Direct costs				Direct and indirect costs			
A. Base case I								
Provider	-39,681	-201,679	-241,360	94	-39,681	-201,679	-241,360	77
Patient & families				0				0
Direct	-3,402	-12,433	-15,835	6	-3,402	-12,433	-15,835	5
Indirect	0	0	0	0	-9,168	-47,551	-56,719	18
Sub-total	**-3,402**	**-12,433**	**-15,835**	**6**	**-12,570**	**-59,984**	**-72,574**	**23**
Total			**-257,195**	**100**			**-313,914**	**100**
B. Base case II								
Provider	0	-15,328	-15,328	96	0	-15,328	-15,328	78
Patient & families				0				0
Direct	0	-592	-592	4	0	-592	-592	3
Indirect	0	0	0	0	0	-3,684	-3,684	19
Sub-total	**0**	**-592**	**-592**	**4**	**0**	**-4,276**	**-4,276**	**22**
Total			**-15,920**	**100**			**-19,604**	**100**

Sources: Tables 6.14- 6.15 and Tables 7.13-7.18.
Note: Grand total may not add up due to rounding.

8.3.1.2 Losses to patients and families

The direct treatment losses to patients and families from -3 cases of VLBW averted was -D3,402 and the loss incurred by patients and their families for the -15 cases of moderate anaemia, -4 severe anaemia cases, -37 inpatient cases averted, and the -5 deaths averted, was -D12,433. The total direct treatment loss from the two conditions was -D15,835. The total treatment loss for Base case I was -D257,197. From this, provider losses represent 94% and the rest is attributed to losses incurred by patients and their families. The details of these results are presented in Table 8.10.

When indirect costs are taken into account, the treatment loss to patients and their families from -3 cases of VLBW averted was -D12,570. The loss incurred by patients and their families for the -15 cases of moderate anaemia, -4 severe anaemia cases, -37 inpatient cases averted, and the -5 deaths averted, was -D59,984.

The total treatment loss from the two conditions (LBW and anaemia) was -D313,914. Out of this, indirect costs represent 18% of this cost and are 78% of the sub-total costs for patients and their family losses.

8.3.2 Results: Base case II

The resource savings realised due to the IPTp intervention for Base case II in terms of savings to the provider, patients, and their families are presented in this sub-section.

8.3.2.1 Losses to the provider

The saving to the provider in VLBW and ELBW cases averted in Base case II was D0. This is because no case was averted for VLBW (Table 8.10). The losses to the provider for treating one OPD anaemia patient case averted and -4 very severe anaemia cases averted was -D15,328. Total losses to the provider because of the IPTp intervention in Base case II remained at -D15,328; which is the sum of the losses from treatment of LBW (i.e. VLBW, ELBW) and anaemia.

8.3.2.2 Losses to patients and families

Considering only direct costs, the losses to patients and their families from cases of VLBW and ELBW were D0. Since there were no cases of VLBW and ELBW averted, it therefore followed that resource losses from treatment were zero. The loss to patients and their families for one OPD anaemia case averted and -4 very severe anaemia case averted was -D592. The total treatment loss for the two conditions (LBW and anaemia) was -D15,920. From this total, provider losses represent 96% and the rest is attributed to losses incurred by patients and their families.

When indirect costs are taken into account, the loss to patients and their families from cases of VLBW and ELBW was again D0 (since there was no case of VLBW and ELBW averted) and the loss to patients and their families for one OPD anaemia case averted and -4 very severe anaemia case averted was -D4,276. Of total direct and indirect costs to patients and families, indirect costs represent -D3,684 (86%). The total treatment loss for the two conditions (LBW and anaemia) was -D19,604 and indirect costs represent 19% of this total. Table 8.10 shows the details of losses to patients and their families.

8.4 SUMMARY

The analysis of resource consequences of IPTp showed that the provider made a total loss of -D241,360 for Base case I. The corresponding loss to patients and their families was -D72,574. Out of this, -D15,835 was direct cost and -D56,719 (18%) was indirect. The total loss incurred in Base case I was -D313,914. The total loss incurred from Base case II was -D19,604, which comprised -D15,328 to the provider and -D4,276 to patients and their families. Of this total, indirect costs represented -D3,684 (19%). The number of cases and deaths averted that led to these losses were -3 LBW and zero deaths for Base case I and the corresponding figures for anaemia were -19 moderate/severe anaemia, -37 very severe anaemia cases and -5 deaths. No cases or deaths were averted for LBW in Base case II and only -3 cases and no deaths were averted from anaemia. The findings of the trial have raised many issues for the CEA and these are discussed in Chapter 10.

CHAPTER 9: COSTS, RESOURCE CONSEQUENCES AND ICER OF IPTp

9.1 INTRODUCTION

The main purpose of this chapter is to pull together all the results from Chapters 6-8 and to estimate costs and resource savings and, where relevant, Incremental Cost-Effectiveness Ratio (ICER) for the IPTp intervention. To estimate these, the costs and effectiveness values estimated earlier for Base cases I and II are put together. Specifically, the cases, deaths and DALYs averted as well as resource savings estimated in Chapter 8 are combined with the IPTp and treatment costs estimated in Chapter 6, and indirect costs from Chapter 7, to calculate the ICERs. The second part of the chapter is devoted to a sensitivity analysis that assesses the robustness of the assumptions. The base discount rate of 3% was used throughout this thesis but the effect of changing that discount rate on costs and consequences was assessed using other discount rates. The various methods of measuring indirect costs were used to assess the susceptibility of the costs and consequences to methods of measuring indirect costs. Other variables tested include referral (transport) and drug costs. On the effectiveness side, sensitivity of the prevalence and case fatality rates for LBW from the literature and those reported in The Gambia (UNICEF, 2000; Okoji and Oruambo, 1992) were tested on the IPTp costs and consequences. The effectiveness rate for primigravidae obtained from the literature and effectiveness rate from the trial for multigravidae were used. These parameters were tested because they are likely to have an effect on the results (Briggs et al, 1994; Briggs and Sculpher, 1995; Briggs and Gray, 1999, Briggs, 2000).

9.2 NET IPTp IMPLEMENTATION COSTS

Table 9.1 contains the IPTp cost for Base case I (multigravidae population), Base case II (only those multigravidae who do not sleep under a bednet) and treatment cost savings that arose because of the intervention. Treatment cost consequences, which were estimated in the latter part of Chapter 8, were combined with the IPTp implementation cost to obtain net costs. The negative signs mean that cases of, and deaths from, LBW and anaemia were more for IPTp than for routine antenatal care, and thus costs are incurred in treating the extra cases compared with the control. These negative cost savings could be regarded as 'losses' in resources which would not have occurred without the intervention.

By only considering direct costs, the IPTp cost, as indicated in Table 9.1, was D964,576 for Base case I. The treatment cost savings from the IPTp intervention for Base case I were -D257,195. The difference of the treatment cost savings and IPTp implementation cost gave the net IPTp costs for Base case I as D1,221,771. When indirect costs are considered in Base case I, the IPTp costs became D1, 573,693 and the treatment cost savings from the IPTp intervention for Base case I were -D313, 914. The difference of the treatment cost savings and IPTp implementation costs gave the net IPTp costs for Base case I as D1,887,607. The details of the estimations are presented in Table 9.1 and summarised in 9.2.

By considering only direct costs, the IPTp costs came to D300,013 for Base case II. The treatment cost savings from the IPTp intervention for the same base case were -D15,920. The difference of the treatment cost savings and IPTp implementation cost gave the net IPTp costs as D315,933. When indirect costs were considered in Base case II, the IPTp cost became D434,016 and the treatment cost savings from the IPTp intervention were -D19,604. The difference of the treatment cost savings and IPTp implementation cost gave the net IPTp costs as D453,620,. The details of the estimation are presented in Table 9.1 and summarised in 9.2.

Table 9.1 Costs and consequences of IPTp

	Base case I (D)	Base case I (D)	Base case II (D)	Base case II (D)
	Direct costs	**Direct and indirect costs**	**Direct costs**	**Direct and indirect costs**
	LBW/Anaemia	**LBW/Anaemia**	**LBW/Anaemia**	**LBW/Anaemia**
Incremental IPTp cost				
Provider				
Recurrent	837,315	837,315	215,681	215,681
Capital	72,808	72,808	72,348	72,348
Sub-total	**910,122**	**910,122**	**288,030**	**288,030**
Patients				
Direct	54,453	54,453	11,983	11,983
Indirect	0	609,117	0	134,004
Sub-total	**54,453**	**663,570**	**11,983**	**145,987**
Incremental IPTp cost (D)	**964,576**	**1,573,693**	**300,013**	**434,016**
Resource savings				
Provider	-241,360	-241,360	-15,328	-15,328
Patient & families				
Direct	-15,835	-15,835	-592.	-592.
Indirect	0	-56,719	0	-3,684
Sub-total	**-15,835**	**-72,554**	**-592**	**-4,276**
Total	**-257,195**	**-313,914**	**-15,920**	**-19,604**
Net IPTp implementation cost (D)	**1,221,771**	**1,887,607**	**315,933**	**453,620**

Sources: 6.11, 7.9-7.18 and 8.10

9.2.1 Cost and consequences of IPTp

The aim of this section is to compare the health outcomes presented in Chapter 8 with the net programme costs shown in Section 9.1. The results are shown in Table 9.2. For Base case I, it is clear that the control, namely routine ANC, dominates, as illustrated by the negative sign, which indicates that rather than reducing the cases of, and deaths from, LBW and anaemia, the IPTp intervention instead led to more cases and deaths. The cases and deaths averted from LBW for Base case I were -3 and zero respectively. The corresponding cases and death from anaemia were -56 and -5. The cases and deaths averted from LBW in Base case II were zero each and -3 and zero respectively (details in Chapter 8).

Table 9.2 Summary of costs and consequences of IPTp

	Base case I (D)		Base case II (D)	
	Direct costs	**Direct and indirect costs**	**Direct costs**	**Direct and indirect costs**
1. IPTp implementation costs	964,576	1,573,693	300,013	434,016
2. Resource savings	-257,195	-313,914	-15,920	-19,604
3. Net costs	1,221,771	1,887,607	315,933	453,620
Health consequences				
Case averted				
LBW	-3	-3	0	0
Anaemia	-56	-56	-3	-3
Deaths Averted				
LBW	0	0	0	0
Anaemia	-5	-5	0	0
4. DALYs	-125.8	-125.8	-0.13	-0.13

Sources Tables 8.4-8.9 and 9.1

9.3 SENSITIVITY ANALYSIS

The cost-effectiveness results presented in the two base cases are not cast in stone because many assumptions (for example, ALoS, CFRs, years lived with disability, etc.) regarding the cost and effectiveness were made. Furthermore, not all the data needed for the analysis were available, which led to the use of additional data from outside the main trial for the analysis. Therefore, there is the need to ascertain how the results may be affected by changes in key assumptions. To assess uncertainties around these assumptions, a series of one-way and some multi-way sensitivity analyses were conducted. One-way sensitivity analysis involves the changing of only one variable at a given point in time and then assessing the effect on costs and consequences (Drummond et al, 1997). Multi-way sensitivity analysis involves changing more than one variable at a time and then assessing their collective impact on the results.

In the case of this study, the key cost variables that were varied included the discount rate, drug prices, introduction of Haemoglobin (Hb) test, wage rates for indirect costs, number of OPD visits, average length of hospital stay and referral transport costs. In the case of health outcomes, the effectiveness and case fatality rates for LBW and anaemia were varied for each condition and then varied simultaneously, and then assessed their effects. There are no known cases of countries where policies of giving SP as IPTp are different between primigravidae and multigravidae.

The implication of giving IPTp to all gravidae was explored in the sensitivity analysis. The average effectiveness rates of IPTp for primigravidae, obtained from the literature, and those obtained from the trial were used with a view to assessing their combined effectiveness (see Table 9.3.2 for details). A description of each variable tested in the sensitivity analysis and the justification for their inclusion are given in Tables 9.3, 9.3.1 and 9.3.2. In the presentation, ICERs are calculated only where the health effects of IPTp are positive.

Table 9.3 Sensitivity analysis: IPTp and treatment costs

Variable	Base case values	Sensitivity analysis values	Justification (s)
One-way sensitivity analysis			
Discount rate	3%	6%, 10% and 16.4%	In order for the results of this study to be comparable to other studies in Africa and other developing countries, the discount rate was varied from the base rate of 3% to 6% and 10%. Furthermore, since the study is in The Gambia, it is appropriate to reflect that country's economic situation in the results by using the real interest rate of 16.4%.
Change in drug price	100%	200%	The high level of the real interest rate at 16.4% is a pointer to unfavourable economic conditions in the country. Given that, and the fact that The Gambia imports all her drugs from third countries means that future price rise is a distinct possibility. Therefore, the cost of drugs (SP) has been doubled and the effect assessed on the result.
Change in drug prices	100%	75%	It is possible that SP could be purchased from local wholesalers rather than importing from abroad. This could lead to substantial savings by the provider. Base on this fact, drug price was reduced by 25% and the effect assessed.
Change in materials and supply costs	0%	100%	Haemoglobin (Hb) tests in theory are supposed to be part of routine antenatal care. However, in practice, Hb tests are limited to certain base health facilities only. The implication of introducing Hb as part of IPTp was explored in sensitivity analysis.
Number of ANC visits	4 visits	2 visits	The WHO-recommended number of doses of SP as IPTp used by most studies is two. To make the results comparable to those that followed the WHO guidelines, it is worthwhile to use the same number of visits.
Opportunity cost (OPA)	D5.79	D3.83, D4.77, D5.14, D5.98, D2.43 D0	The base wage rate used to estimate indirect costs was produced by using the female wage rates within the study site through the opportunity cost approach. In line with the objectives of this study, it is necessary to use the rates reached by each of the appropriate approaches, using wage rates such as that of males (D3.83), average of male and female wage rate (D4.77) (opportunity cost), market replacement wage of a specialist household worker such as maid (D5.14), market replacement wage using generalist household worker's wage (D5.98), human capital approach (D2.43) and frictional cost approach (0).
OPD visits, average length of stay (ALoS)	7, 21 and 28	2 visits, 3.5,10.5 and 14	The average length of stay for anaemia (7 days), VLBW (21 days) and ELBW (28 days) seem to be high for this category of inpatients, which could be attributed to poor medical standards in The Gambia. However, with time, this could be reduced to the level of other countries within the sub-region. Hence the need to assess the effect of the changes on costs, consequences and where possible ICERs.
Referral costs	D1,119 & D8,650	D595 & D4,325	There is concern amongst the health facility heads that Riders for Health (RFH) charge too much for their services, to a point that a review of their contract seems very likely. This is necessary because a review of the contract could in turn lead to the review of the charges.
Proportion of non-bednet users	22%	61.4%	The latest proportion of non-bednet users in NBE and LRD was 61.4%. This proportion of women not sleeping under bednets was reported in a recently published report by the Malaria Control Unit (MCU) of the DoSH (DoSH, 2004) which puts the non-bednet users in LRD and NBE at 49.9% and 72.9% respectively. The average of these has been applied here to assess their impact on the results.

Table 9.3.1 Sensitivity analysis: effectiveness

Variables	Base case values	Sensitivity analysis values	Justification (s)
Change in DALY parameters			
Change in discount rate	3%	6%, 10% and 16.4%	It is worthwhile to assess the effect of changes in discount rates on the DALYs averted and the ICERs as recommended in the literature (Fox-Rushby and Hanson, 2001).
LBW (years lived with disability)	5 yrs	9 yrs	The years lived with disability for VLBW and ELBW was increased from 5 to 9 years. This is useful in making the results comparable to other studies (Fox-Rushby and Hanson, 2001; Anand and Hanson, 1997).
Age at onset of anaemia	30 yrs	26.8 yrs	To assess the effect of changes in age of women at the onset of anaemia on DALYs and ICERs; the median age of 30 used in the base cases was changed to the mean age of 26.8 (Fox-Rushby and Hanson, 2001; Anand and Hanson, 1997).
Multi-way sensitivity analysis			
Prevalence rates for LBW			
LBW (Base case I)	7.1%	17.4%	The average prevalence rate of LBW in NBE and LRD was 17.4% (MICS) (UNICEF, 2000).
LBW (Base case II)	7.4%	17.4%	
VLBW	0.3%	3.8%	These are the distribution of VLBW and ELBW cases compiled by the candidate from the AFPRCH.
ELBW	0%	2.4%	
Case Fatality Rate (CFR) LBW			
VLBW	12.5	53.5%	It is important to compare the national case fatality rates with those from the literature for easy comparison with other studies conducted elsewhere (Okoji and Oruamabo, 1992).
ELBW	100%	89.7%	
Prevalence of anaemia			
Anaemia (Base case I)	9%	83%	The prevalence rate of anaemia in The Gambia was used instead of the trial rate in order to assess the robustness of the trial rate (NaNA/MRC, 2001)
Anaemia (Base case II)	16%	83%	
Severe anaemia (incl. very	1.2%	6%	
Moderate anaemia	7.6%	83%	
Case Fatality Rate (CFR)			
Severe anaemia (AFPRCH)	11.8%	11.8%	The Case Fatality Rate (CFR) for anaemia in NBE was used as the uniform rate for both hospitals instead of using different rates for each hospital (DoSH, 2001).
Severe anaemia (RVTH))	2.5%	11.8%	

Table 9.3.2 Multi-way Sensitivity analysis: effectiveness

Multi-way sensitivity analysis			
Primigravidae & Multigravidae: birth weight	**Base case values**	**Sensitivity analysis values**	**Justification (s)**
Base case I			
LBW (IPTp intervention)	5.4%	7.9%	The average effectiveness rates from the trial and Rogerson et al (2000) for IPTp ((5.4+10.3)/2 = 7.9%) and control ((7.1 + 23)/2 = 15.1) were used to assess the cost-effectiveness of IPTp for LBW for all pregnant women sleeping under ITNs.
LBW (Control)	7.1%	15.1%	
Base case II			
LBW (IPTp)	4.3%	7.3%	The average effectiveness rates from the trial and Rogerson et al (2000) for IPTp ((4.3 + 10.3)/2 = 7.3%) and control ((7.4 + 23)/2 = 15.2) were used to assess the cost-effectiveness of IPTp for LBW for all pregnant women.
LBW (Control)	7.4%	15.2%	
Distribution			
VLBW (IPTp)	0.47%	2.1%	The average effectiveness rates from the trial and AFPRCH for IPTp ((0.47+8.9)/2 = 2.1) and Control ((0.32+13.1)/2 = 2.1) were used to assess the cost-effectiveness of IPTp for LBW for all pregnant women.
VLBW(Control)	0.32%	2.1%	
ELBW (IPTp)	0%	1.2%	The average effectiveness rates from the trial and that compiled from AFPRCH for IPTp ((0+2.4)/2 = 1.2) and Control ((0+2.4)/2 = 1.2) was used to assess the cost-effectiveness of IPTp for LBW for all pregnant women. The AFPRCH data was used because the trial did not make provision for the collection of CFRs.
ELBW (Control)	0%	1.2%	
Case Fatality Rate			
VLBW	12.5%	33%	The average case fatality rates for the trial and that from Okoji & Oruamabo (1992) for IPTp ((12.5+53.5)/2 = 33) and Control ((89.7+100)/2 = 94.9) were used in order to assess the cost-effectiveness of IPTp for LBW for all pregnant women. The main IPTp trial did not make provision for collecting case fatality data. Therefore, for the purpose of CEA, AFPRCH and other secondary data were used instead (See Section 5.11.2) for details.
ELBW	100%	94.9%	
Primigravidae & Multigravidae: anaemia			
Anaemia: Base case I			The average prevalence rates of anaemia (75.6%) reported by Shulman et al, (1996) and from the trial for IPTp ((11 + 75.6)/2 = 43.3) and control ((9 + 75.6)/2 = 42.3) for Base cases were used to estimate the cost-effectiveness of anaemia for all pregnant women.
Anaemia (IPTp)	11%	43.3%	
Anaemia (Control)	9%	42.3%	
Anaemia: Base case II			The same was repeated for Base case II: IPTp ((13+75.6)/2 = 44.2% and Control ((16 + 75.6/2 = 45.8%)
Anaemia (IPTp)	13%	44.2%	
Anaemia (Control)	16%	45.8%	
Severe anaemia			The average prevalence rates for severe anaemia for IPTp ((1.2 + 14.5)/2 = 7.9) and Control (1.2 + 23.7)/2 = 12.8) reported by (Shulman et al, 1999) and from the trial were used in order to estimate the cost-effectiveness of anaemia for all pregnant women.
Severe anaemia (IPTp)	1.9%	7.9%	
Severe Anaemia (Control)	1.2%	12.8%	
Moderate anaemia ((IPTp)	8.7%	42.2%	The average prevalence rates of anaemia (75.6%) reported by Shulman et al, (1996) and the effectiveness rates reported by the trial for IPTp ((8.7+75.6)/2 = 42.2) and Control ((7.6 + 75.6)/2 = 41.6) for Base cases I and II were used to estimate the cost-effectiveness of anaemia for all pregnant women.
Moderate anaemia (Control)	7.6%	41.6%	
Case Fatality rate			
AFPRCH	11.8%	14%	The average case fatality rates of 8-20% ((8+20)/2 = 14) from Shulman et al, (1996) were used instead of the rates from AFPRCH (11.8%) and RVTH (2.5%) to estimate the cost-effectiveness of anaemia for all pregnant women.
RVTH	2.5%	14%	
LBW and anaemia	Direct and D5.79 (indirect costs)	D0 D3.83, D4.77, D5.14, D5.98, D2.43	Sensitivity analysis was conducted by changing costs by including and excluding indirect costs for all pregnant women and assessed their effects on ICERs. Furthermore, the effects of changes in indirect costs (wage rates) were assessed. This will make it possible to compare this study with similar studies in developing countries and to assess the effects of using various wage rates of valuing indirect costs on ICERs.

9.3.1 Change in discount rate, prices of drugs, materials and supplies use, number of doses

Change in discount rate has its first impact on the IPTp costs, which in turn leads to a change in the net IPTp cost. Changing the base discount rate from 3% to 6% led to a modest increase in the IPTp costs by 0.3% for Base case I as illustrated in Table 9.4, Part A. While the resource savings remained unchanged, these changes led to 0.2% increases in the net IPTp costs. By further raising the discount rate from 3% to 10%, the IPTp cost for Base case I went up by a mere 1% and the corresponding increase in net costs was 1%. The final change in the discount rate was to raise it from the base rate of 3% to 16.4% (real interest rate in The Gambia). The result of the change was an increase in IPTp intervention costs by 1% from the base case. The change in discount rate led to corresponding increases in net costs for Base case I. The details of these results and the resource savings are in Table 9.4, Part A.

Drugs are an important component of the IPTp intervention and so any variation in price first affects the IPTp cost with a ripple effect on the net costs. Drug cost represents 73% of the incremental IPTp cost in Base case I (Section 6.3.2.1, Chapter 6). Given the high real interest rate in The Gambia, which is a pointer to poor economic conditions, a future increase in drug prices by 100% is realistic. The effect of an upward movement of drug prices by 100% led to a 42% increase in IPTp cost for Base case I. These changes in turn led to 35% increases in net IPTp costs for Base case I as indicated in Table 9.4, Part A.

The possibility of switching suppliers from outside to local wholesalers exists. This is also tested in sensitivity by reducing the drug price by 25% from the trial price as there will no longer be the freight cost. This will likely lead to reduction in drug price. The change in drug price from the base price of D12 to D9 per woman led to changes in the proportion of recurrent cost taken up by drugs from 73% to 67% for Base case I. The new incremental IPTp cost as a result was D1,406,659 and D797,542 for Base case I with and without indirect costs respectively. The net IPTp implementation costs were D1,720,573 and D1,054,737 with and without indirect costs for Base case I respectively. Reduction in SP price by 25% led to 11% decrease in IPTp costs. With resource savings remaining the same, the net IPTp costs also decreased by 9%. The results of changing the SP prices by 25% are illustrated in Table 9.4, Part A.

Haemoglobin (Hb) testing is considered part of routine antenatal care (ANC) rather than IPTp per se. However, where it is not part of routine ANC, all the related costs of Hb testing ranging from materials and supplies to small equipment such as sharps and sharp boxes for disposal of sharps will have to be taken on board. Materials and supplies costs for Hb testing were not included in the cost estimation of the total IPTp costs for Base case I. Introducing the Hb test in IPTp led to over 500% increase in IPTp costs and the corresponding increases in the net costs were 434%. The details of the changes in the two variables are presented in Table 9.4, Part A.

The WHO recommended number of doses for SP as IPTp is two. The results of changing the number of doses from four (in the IPTp trial) to two are indicated in Table 9.4, Part A. The average number of visits to ANC in The Gambia is 3.4. Therefore, reducing the number of doses of SP to two fits into this average. It would therefore not require the extra 0.6 visit with all the associated costs. Furthermore, the additional time required for IPTp from the staff and supervisors as well as drugs, and the waiting time at the ANC clinic, will be reduced. The effect of this change on IPTp cost was a 41% reduction in Base case I. The effects of these changes on net IPTp costs were a 34% reduction for Base case I (Table 9.4, Part A).

es in discount rate, prices of drugs, materials and supplies use, number of doses

Change in discount rate from 3% to 6%		Change in discount rate from 3% to 10%		Change in discount rate from 3% to 16.4%		100% increase in drug (SP) price		25% decrease in drug (SP) price		Introduction of Haemoglobin test (Material & Supplies costs)		Change in doses from 4-2	
D	%	D	%	D	%	D	%	D	%	D	%	D	%
1,577,649	0.3	1,582,461	1	1,590,920	1	2,241,829	42	1,406,659	-11	9,762,101	520	923,546	-41
-313,914	0	-313,914	0	-313,914	0	-313,914	0	-313,914	0	-313,914	0	-313,914	0
1,891,563	0.2	1,896,375	1	1,904,834	1	2,555,743	35	1,720,573	-9	10,076,015	434	1,237,460	-34
437,929	1	443,180	2	451,314	4	581,016	34	397,281	-8	2,238,463	416	275,416	-37
-19,604	0	-19,604	0	-19,604	0	-19,604	0	-19,604	0	-19,604	0	-19,604	0
457,533	1	462,784	2	470,918	4	600,620	32	416,885	-8	2,258,067	398	295,020	-35

As illustrated in Table 9.4, Part B, the results of changing the base discount rate from 3% to 6% led to a modest increase in the IPTp costs of 1% for Base case II. While the resource savings remained unchanged, these changes led to 1% increases in the net IPTp costs. By further raising the discount rate from 3% to 10%, the IPTp cost for Base case II went up by 2%. The corresponding change in net costs was also 2%. The final variation in the discount rate was to raise it from the base rate of 3% to 16.4% (real interest rate in The Gambia). The result of the change was an increase in IPTp intervention costs by 4% in Base case II. This change in discount rate led to corresponding increases in net costs. The details of these results and the resource savings are in Table 9.4, Part B.

Drug cost represents 51% of the incremental IPTp cost in Base case II (Section 6.3.3.1, Chapter 6). The effect of an upward movement of drug prices by 100% led to a 34% increase in IPTp cost for Base case II. These changes in turn led to 32% increases in net IPTp costs for Base case II as indicated in Table 9.4, Part B.

Changing the drug price by 25% from the trial price led to changes in the proportion of recurrent cost taken up by drugs from 51% to 44% for Base case II. The new incremental IPTp costs as a result, were D1,720,573 and D416,885 for Base case II with and without indirect costs respectively. The reduction in drug price led to 8% reduction in IPTp costs while the resource savings remained the same for Base case II. The effect of both these on net IPTp cost was an 8% decrease.

As was the case in Base case I earlier, materials and supplies costs for Hb testing were not included in the estimation of the total IPTp costs for Base case II. Introducing the Hb test in IPTp led to over 400% increase in IPTp costs for Base cases II. The corresponding increases in the net costs are 398% for Base case II. The details of the changes in the two variables are presented in Table 9.4, Part B. The effect of changing the number of visits from four to two on IPTp cost was a 37% reduction in Base case II. The effects of these changes on net IPTp costs were 35% decrease (Table 9.4, Part B).

9.3.2 Changes in wage rates

This section assesses the effects of applying the wage rates generated by using the various methods of measuring indirect costs, on IPTp cost, and resource consequences. These changes affect IPTp costs as well as resource losses with their combined effects on the net costs. These methods include opportunity cost (using male wage rate and average of male and female wage rates), market replacement, human capital and the frictional costs methods. The method used in the base case is the opportunity cost approach, using average female wage rate in rural Gambia.

When the male wage rate of D3.83 was used, it led to a 13% reduction in IPTp costs for Base case I. The change also led to 6% decrease in resource losses for Base case I. The combined reduction of the IPTp costs and resource losses was 12% reduction in net costs. Further changing the wage rate to the average of male and female wages (4.77) in the study site produced a decrease of 7% in the IPTp costs for Base case I. The effect of these changes was a 3% decrease in resource losses. The combined effects of these changes led to a 6% decrease in net costs. The details are in Table 9.5, Part A.

By changing the wage rate from D5.79 to that of a specialist wage rate (D5.14), the IPTp costs decreased by 4% for Base case I. The consequence of the change in wage rate on resource losses was a 2% decrease. The combined effect of these changes on the net cost was 4% decrease in Base case I as illustrated in Table 9.5, Part A. The use of a wage rate generated by using the average wages of several generalist household workers led to a minimal increase of the IPTp costs for Base case I by 1% and an increase in resource losses by 1%. The eventual change on net IPTp costs was also an 1% increase, as illustrated in Table 9.5, Part A.

The estimated wage rate using the human capital approach was D2.43. A change in the base wage rate from D5.79 to D2.43 led to a 22% reduction in the net IPTp cost for LBW in Base case I. The effect of the change on resource consequences was a 9% reduction, as indicated in Table 9.5, Part A. The overall reduction in net costs was 20%.

The strict use of the HCA means that the resource consequences for LBW should be extrapolated to 57 years (average life expectancy in The Gambia for males and females) for all fatal cases from age 0 for LBW. For any fatal LBW case, age 0-6 represents pre-school age and 7-17 years is school-going age including vocational education. However, the estimation of school days lost is beyond the scope of this study. Therefore, the loss of productivity is estimated from 18 to 57 years. Since the sex ratio in The Gambia is 1:1, equal numbers of boys and girls are alive at any given point in time.

It was assumed that all fatal LBW cases lose the opportunity to earn D22,176 per annum, which is the annual pay for a nurse midwife in the Farafenni hospital. Therefore, the Net Present Value (NPV) for the deferred loss of earnings from 18 years to 57 years (i.e. over 39 years) discounted at 3% is D361,779 per LBW death. In the case of this study, there was no fatal LBW case and so using HCA affects only the wage rate D2.43 as explained earlier.

The modal age for females in the trial is 30 and the retirement age is 60. It is therefore assumed that women who died of anaemia at the modal age of 30 would, if alive, be productive up to 59 years. To estimate the potential productivity loss, the average hourly wage rate of D2.43 was multiplied by 10.7 hours (i.e. average number of hours work per day) for 29 years discounted at a rate of 3%. The undiscounted amount for the -5 women was -D1,376,103 and the discounted amount was -D584,330. The resource losses and the the net costs were –D895,407 and D2,115,623 respectively (See Table 9.5). Applying the strict form of HCA resulted in a 185% increase in resource losses leading to 12% increase in net losses for Base case I. The corresponding changes in Base case II were 3% and 17% decreases. In the sensitivity analysis using the strict form of HCA, five more very severe anaemia deaths occurred due to IPTp in Base case I. The resource losses due to these deaths projected for 29 years and those due to additional cases of LBW and anaemia led to 185% increase in resource losses for Base case I leading to 12% increase in net costs (See Section 9.3.2 & Table 9.5). In Base case II, only one case of moderate anaemia was averted leading to resource saving of 3% leading to 17% decrease in net costs. This is what explains the movement of resource losses/savings and net costs of Base case I and II in different directions.

According to the proponents of FCA, the approach does not take onboard any work outside the formal working environment, which means the value attached to unpaid work is zero (Section 2.3.3, Chapter 2; Table 7.8). In effect, using the FCA is equivalent to using direct costs only. By excluding indirect costs therefore means the 90-day frictional period for replacing a worker does not arise here because there was no formal work. By varying the unpaid wage rate to zero, the IPTp cost and resource losses for Base case I dropped by 39% and 18% respectively. The combined effect of these two reductions was a 35% decrease in net cost. All these are illustrated in Table 9.5, Part A.

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ıges according to methods of estimating indirect costs

Sensitivity analysis values													
unity cost roach ge rate) of 3.83		Opportunity cost approach (average wage rate for male & female) of D4.77		Replacement cost approach (specialist's maid wage rate) of D5.14		Replacement cost approach (generalist wage rate) of D5.98		Human capital approach (D2.43)		Human capital approach (D2.43) (Strict form)		Frictional Cost Approach (0)	
	%	D	%	D	%	D	%	D	%	D	%	D	%
5	-13	1,466,792	-7	1,505,766	-4	1,594,294	1	1,220,216	-22	1,220,216	-22	964,576	-39
7	-6	-304,395	-3	-308,079	-2	-316,398	1	-286,643	-9	-895,407	185	-257,195	-18
2	-12	1,771,187	-6	1,813,845	-4	1,910,692	1	1,506,859	-20	2,115,623	12	1,221,771	-35
	-10	410,498	-5	419,072	-3	438,548	1	356,252	-18	356,252	-18	300,012	-31
	-6	-18,994	-3	-19,234	-2	-19,776	1	-17,592	-10	-18,972	-3	-15,920	-19
	-10	429,492	-5	438,306	-3	458,324	1	373,844	-18	375,224	-17	315,932	-30

When the male wage rate of D3.83 was used, it led to 10% reduction in IPTp costs for Base case II. The change also led to 6% decrease in resource losses. The combined reduction of the IPTp cost and resource losses was a 10% reduction in net costs for Base case II.

Further changing the wage rate to the average of male and female wages (4.77) in the study site produced a decrease of 5% in the IPTp costs for Base case II. The effect of these changes on net costs was a 3% decrease in resource losses. The combined effects of these changes led to 5% decrease in net costs. The details are in Table 9.5, Part B.

By changing the wage rate from D5.79 to that of a specialist (D5.14), the IPTp costs decreased by 3% for Base case II. The consequence of the change in wage rate on resource losses was a 2% decrease. The combined effect of these changes on the net cost was a 3% decrease as illustrated in Table 9.5, Part B. The use of a wage rate generated by using the average wage rate of several generalist household workers led to a minimal increase of the IPTp costs for Base case II by 1% and an increase in resource losses by 1%. The eventual change on net IPTp costs was also 1% increase for Base case II as illustrated in Table 9.5, Part B. The procedures followed in conducting sensitivity analysis using HCA (simple and strict) and FCA for Base case I are the same as was done for Base case II. The details of the results are indicated in Table 9.5, Part B.

9.3.3. Changes according to reductions in the number of OPD visits and ALoS for IPD, referral transport costs and changes in non-bednet use

Changing OPD visits and average length of stay (ALoS) affect net costs through changes in resource savings. Varying the number of outpatient visits and the ALoS by 50% (i.e. from four to two visits for outpatient anaemia, from seven to 3.5 days for inpatient anaemia, from 21 to 10.5 for VLBW and from 28 to 14 for ELBW cases). The resource losses to the provider and patients decreased by 27% for Base case I. The overall effect of the changes on the net costs was a 4% decrease as indicated in Table 9.6, Part A. Reducing the referral transport cost by 50% resulted in a 15% reduction in resource losses for Base case I, which in turn led to 2% decrease in net cost. Changing the proportion of non-bednet users from 22% to 61.4% in the trial site only affects Base case II and is discussed in the next paragraph.

Table 9.6 Effects on costs due to reductions in OPD visit, ALoS, referral transport costs and changes in non-bednet use

Costs	Base case values	Sensitivity analysis values					
		Reduction in OPD visits and ALoS by half		Reduction in referral transport cost by half		Change in non-bednet use (61.4%)	
		Base case I		Base case I		Base case I	
	D	D	%	D	%	D	%
A. Base case I							
IPTp cost	1,573,693	1,573,693	0	1,573,693	0	-	-
Resource savings/losses	-313,914	-230,215	-27[15]	-267,134	-15	-	-
Net costs	1,887,607	1,803,908	-4	1,840,827	-2	-	-
B. Base case II							
IPTp cost	434,016	434,016	0	434,016	0	1,030,315	35
Resource savings/losses	-19,604	-11,636	-41	-17,368	-11	1,773	101
Net costs	453,620	445,652	-2	451,384	-0.1	1,028,542	46

The variable changes in Base case I are the same for Base case II. The resource losses to the provider and patients as a result of decreasing OPD visit and ALoS by half led to a decrease by 41% in Base case II. The overall effect of the changes on the net costs was a 2% decrease as indicated in Table 9.6, Part B. Reducing the referral transport cost by 50% resulted in an 11% reduction in resource losses for Base case II which in turn led to 0.1% decrease in net costs.

Non-bednet use appears to be an important determinant of the effectiveness of the IPTp intervention (Mbaye et al, 2006). Changing the proportion of non-bednet users from 22% to 61.4% in the trial site affects only Base case II in terms of costs, resource savings and health outcomes as indicated in Table 9.6, Part B. The change led to a 35% increase in IPTp cost and 46% increase in net cost via a 101% increase in resource losses. The consequences of the change on all the variables are presented in Table 9.6, Part A.

9.3.4 Changes in key DALY parameters

The variables tested were those related to estimating DALYs. The parameters varied included the discount rate; years lived with disability for VLBW and ELBW, which were changed from five to nine years; and age at onset of anaemia from 30 to the average age of 26.8.

[15] The increases or decreases that occurred because of substituting the base case values with the new ones in the sensitivity analysis are indicated by the percentages in the table.

The effect of each of these changes on the total DALY averted for the two base cases was assessed (See Table 9.7, Part A for details). By changing the discount rate used to estimate DALYs from 3% to 6%, DALYs averted for Base case I decreased by 27%. Further changing the discount rate from 3% to 10% affected only DALYs averted for Base case I (48% decrease). Changing the discount rate again to 16.4% also affected only DALYs averted for Base case I (64% decrease) (See Table 9.7, Part A).

LBW babies, especially VLBW and ELBW, were assumed to live with disability up to five years. This was changed to nine years and the effect assessed on DALYs. The change in years lived with disability led to a 1% increase in DALYs for Base case I as illustrated in Table 9.7, Part A. Changing the years of onset of anaemia from the modal age of those who participated in the trial (30 years), to the mean age of 26.8 years led to a 10% increase for Base case I.

Table 9.7 Effects on DALYs due to changes in discount rate, years lived with LBW disability and age from the onset of anaemia

DALYs	Base case values	Sensitivity analysis values									
		Change in discount rate from 3%-6%		Change in discount rate from 3%-10%		Change in discount rate from 3%-16.4%		Years lived with disability from 5-9 years		Age at onset of anaemia from 30-26.8 years	
			%		%		%		%		%
A. Base case I											
DALYs	-125.8	-92.6	-27[16]	-66	-48	-45	-64	-127	1	-138	10
B. Base case II											
DALYs	-0.13	-0.13	0	-0.13	0	-0.13	0	-0.13	0	-0.13	0

By changing the discount rate or DALYs used to estimate DALYs from 3% to 6%, DALYs averted for Base case II remained unchanged. Further changing of the discount rate from 3% to 10% and from 3% to 16.4% left DALYs averted for Base case II unaffected (Table 9.7, Part B). The changes in years lived with disability by LBW babies and years of onset of anaemia from the modal age of those who participated in the trial (30 years), to the mean age of 26.8 years led to no change in Base case II as illustrated in Table 9.7, Part B.

[16] The increases or decreases that occurred because of substituting the base case values with the new values in the sensitivity analysis are indicated by the percentages in the table.

9.3.5 Changes in prevalence and case fatality rates for both LBW and anaemia

In order to re-assess effectiveness, prevalence and case fatality rates for LBW and anaemia were changed simultaneously. The prevalence rate of LBW was changed from the original trial rate of 3% to 17.4% (DoSH, 1999) and the prevalence rates for VLBW and ELBW were changed to 3.8% and 2.4% respectively. The case fatality rates for VLBW and ELBW were also changed to 53.5% and 89.7% respectively. The prevalence rate of anaemia as a whole was changed from the trial rates of 9% and 16% for Base cases I and II respectively to 83% (DoSH, 1999) and those for severe and very severe anaemia to 1.5% and 4.5% respectively. This is in line with the WHO (1999) estimate that 75% of all severe anaemia cases are very severe. The prevalence rate for moderate anaemia was also changed to 83% and the case fatality rates for anaemia were made uniform across the country using the LRD rate of 11.8% (DoSH, 1999).

The cases of LBW averted changed from -3 to 164 and the number of deaths averted was 383 against zero for the base value. The DALYs averted as a result of the changes were 5,770 for Base case I. The details of the health outcomes for the changes in prevalence and case fatality rates for anaemia are presented in Table 9.8.

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nges in prevalence and case fatality rates

Base Case I				Base case II					
s	Sensitivity analysis values			Base case values			Sensitivity analysis values		
DALYs averted	Cases averted	Deaths averted	DALYs averted	Cases averted	Deaths averted	DALYs averted	Cases averted	Deaths averted	DALYs averted
	164	189	-	0	0		37	41	-
	0	194	-	0	0		39	4	-
	164	**383**	-	0	0		**76**	**45**	-
	-15	-	-	1	0		63	-	-
	199	-	-	0	0		44	-	-
	1670	223	-	-4	0		364	49	-
	73	10	-	0	0		16	18	-
	1,927	**233**	-				**487**	**67**	-
-125.8	-	-	**5,770**			**0.13**	-	-	**1,270**

For Base case II, the cases and deaths averted from LBW were 76 and 45 respectively. The DALYs averted, because of the changes, were 1,270 for Base II. The details of the health outcomes for the changes in prevalence and case fatality rates for anaemia are presented in Table 9.8.

9.3.6 Effects on costs and DALYs of simultaneously changing the prevalence and case fatality rates

The consequences of changing both the prevalence and case fatality rates are stated in Table 9.9, Part A. The changes were first effected for LBW only, second for anaemia only, and then simultaneously for LBW and anaemia. The results of the change for LBW only led to DALYs averted of 13,279 for Base case I. For anaemia, DALYs averted as a result of the changes was 5,570 for Base cases I. The third scenario was to change the prevalence and case fatality rates for LBW and anaemia leading to DALYs averted of 19,175. The details of these results are presented in Table 9.9, Part A. It should be noted that with these adjusted prevalence and case fatality parameters, IPTp was dominant (resource savings exceeded implementation costs).

Table 9.9 Effects on costs and DALYs of simultaneously changing the prevalence and case fatality rates

Costs	Base case values	Sensitivity analysis values		
		Changes in prevalence and case fatality rates for LBW.	Changes in prevalence and case fatality rates for anaemia	Changes in prevalence and case fatality rates for LBW and anaemia
	D	D	D	D
A. Base case I				
IPTp cost	1,573,693	1,573,693	1,573,693	1,573,693
Resource savings/losses	-313,914	1,893,990	10,978,827	13,186,731
Net costs	1,887,607	-320,297	-9,405,134	-11,613,038
DALYs	-125.8	13,279	5,570	19,175
B. Base case II				
IPTp cost	434,016	434,016	434,016	434,016
Resource savings/losses	-19,604	1,753,743	3,358,616	5,131,963
Net costs	453,620	-1,319,727	-2,924,600	-4,697,947
DALYs	0.13	672	1,270	1,942

The results of the change for LBW only led to DALYs averted of 672 for Base case II. For anaemia, DALYs averted as a result of the changes were 1,270. The third scenario was to change the prevalence and case fatality rates for LBW and anaemia leading to DALYs averted of 1942, details of which are presented in Table 9.9, Part B. IPTp again was dominant.

9.3.7 Prevalence and case fatality rates for primigravidae and multigravidae

The results of changing the prevalence rates in the base case to the average rates of primigravidae and multigravidae on costs and health consequences are given in Tables 9.10 and 9.12 respectively with cost calculations shown in Table 9.11A and 9.11B. The assumptions invoked in the sensitivity analysis by giving IPTp to all pregnant women were to vary the prevalence and case fertility rates from the base case rates (trial rates) to the average of the trial and those obtained from the literature or secondary data from Gambia for LBW and Anaemia. Specifically, the effectiveness rates for Base cases I and II for LBW for IPTp and control were changed from the base case rates to the average effectiveness rates from the trial and Rogerson et al (2000). In the case of VLBW and ELBW, the base case rates for both IPTp and control were changed to the average rates from the trial and AFPRCH and the care fatality rates from the base case rates to the average case fatality rates from the trial and Okoji and Oruamabo (1992). In the case of anaemia (moderate, severe and very severe), Base cases I and II effectiveness rates were changed to the average prevalence rates of the trial and Shulman et al (1996). The base case fatality rates were also changed to the average case fatality rates of the trial and Shulman et al, (1996). The details of these assumptions are shown in Table 9.3.2. The results of the sensitivity analysis showed that 78 cases of and 99 deaths from LBW were averted for Base case I. The corresponding health consequences for Base case II are shown in Table 9.10.

Table 9.10 Summary of health consequences of giving IPTp to all pregnant women (Base cases I & II)

	Base case values		Sensitivity analysis values	
	Base case I	**Base case II**	**Base case I**	**Base case II**
Health consequences				
Cases averted				
LBW	-3	0	78	19
Anaemia	-56	-3	975	290
Deaths Averted				
LBW	0	0	99	24
Anaemia	-5	0	151	41
DALYs	-125.8	-0.13	**4,767**	**1,266**

With only direct costs considered, net costs were -D5,768,324 for Base case I. By considering indirect costs, net costs increased to -D6,330,532. The net costs generated by using the various wage rates in the sensitivity analysis fluctuated around the base values. The net costs were higher for wage rates above the base rate and the converse was true when wage rates lower than the base rate of D5.79 were used. The DALYs averted were 4,767.

In Base case II, the ICERs estimated without and with indirect costs followed the same pattern as was the case in Base case I. The only difference was that net costs in Base case II were lower than those obtained for Base case I.

Therefore, when IPTp is given to all pregnant women (primigravidae and multigravidae), it was found to dominate the status quo of ANC without IPTp. The DALYs averted were 1,266. The details are indicated in Table 9.11 Part B and calculations in Table 9.11B.

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in Dalasis) and consequences of giving IPTp to all pregnant women (Base case I)

ithout ect costs	With Indirect costs	Sensitivity analysis by changing the wage rates				
	Base case wage rate	Opportunity cost approach (male wage rate)	Opportunity cost approach (average wage rate)	Replacement cost approach (Specialist's maid wage rate)	Replacement cost approach (Generalist wage rate)	Human capital approach
	D5.79	D3.83	D4.77	D5.14	5.98	D2.43
6,094	1,106,094	1,106,094	1,106,094	1,106,094	1,106,094	1,106,094
,150	72,150	72,150	72,150	72,150	72,150	72,150
78,244	**1,178,244**	**1,178,244**	**1,178,244**	**1,178,244**	**1,178,244**	**1,178,244**
,751	72,751	72,751	72,751	72,751	72,751	72,751
0	812,142	537,469	669,070	720,969	838,792	340,847
,751	884,893	610,220	741,822	793,720	911,544	413,598
50,995	**2,063,137**	**1,788,464**	**1,920,066**	**1,971,964**	**2,089,788**	**1,591,842**
75,238	6,675,238	6,675,238	6,675,238	6,675,238	6,675,238	6,675,238
4,081	344,081	344,081	344,081	344,081	344,081	344,081
0	1,374,350	933,612	1,144,091	1,228,092	1,416,635	629,265
4,081	**1,718,431**	**1,277,693**	**1,488,172**	**1,572,173**	**1,760,716**	**973,346**
19,319	**8,393,669**	**7,952,931**	**8,163,410**	**8,247,411**	**8,435,954**	**7,648,584**
68,324	**-6,330,532**	**-6,164,467**	**-6,243,344**	**-6,275,447**	**-6,346,166**	**-6,056,742**
,767	**4,767**	**4,767**	**4,767**	**4,767**	**4,767**	**4,767**

in Dalasis) and consequences of giving IPTp to all pregnant women (Base case II)

hout ct costs	With Indirect costs	Sensitivity analysis by changing the wage rates				
	Base case wage rate	Opportunity cost approach (male wage rate)	Opportunity cost approach (average wage rate)	Replacement cost approach (Specialist's maid wage rate)	Replacement cost approach (Generalist wage rate)	Human capital approach
	D5.79	**D3.83**	**D4.77**	**D5.14**	**5.98**	**D2.43**
,763	277,763	277,763	277,763	277,763	277,763	277,763
411	72,411	72,411	72,411	72,411	72,411	72,411
,174	**350,174**	**350,174**	**350,174**	**350,174**	**350,174**	**350,174**
005	16,005	16,005	16,005	16,005	16,005	16,005
)	178,672	118,244	147,196	158,614	184,535	74,987
005	194,677	134,249	163,202	174,619	200,541	90,992
,179	**544,851**	**484,423**	**513,376**	**524,793**	**550,715**	**441,166**
4,790	1,564,790	1,564,790	1,564,790	1,564,790	1,564,790	1,564,790
375	95,375	95,910	95,910	95,910	95,910	95,910
)	372,812	254,150	310,355	333,066	384,258	159,424
375	**468,187**	**350,060**	**406,265**	**428,976**	**480,168**	**255,334**
,165	**2,032,977**	**1,914,850**	**1,971,055**	**1,993,766**	**2,044,958**	**1,820,124**
3,986	**-1,488,126**	**-1,430,427**	**-1,457,679**	**-1,468,973**	**-1,494,243**	**-1,378,958**
66	**1,266**	**1,266**	**1,266**	**1,266**	**1,266**	**1,266**

onsequences of giving IPTp to all pregnant women

Without ndirect costs	With Indirect costs	Sensitivity analysis by changing the wage rates					
	Base case wage rate	Opportunity cost approach (male wage rate)	Opportunity cost approach (average wage rate)	Replacement cost approach (Specialist's maid wage rate)	Replacement cost approach (Generalist wage rate)	Human capital approach	
0	D5.79	D3.83	D4.77	D5.14	5.98	D2.43	
1,250,995	2,063,137	1,788,464	1,920,066	1,971,964	2,089,788	1,591,842	
7,019,319	8,393,669	7,952,931	8,163,410	8,247,411	8,435,954	7,648,584	
-5,768,324	-6,330,532	-6,164,467	-6,243,344	-6,275,447	-6,346,166	-6,056,742	
4,767	4,767	4,767	4,767	4,767	4,767	4,767	
366,179	544,851	484,423	513,376	524,793	550,715	441,166	
1,660,165	2,032,977	1,914,850	1,971,055	1,993,766	2,044,958	1,820,124	
-1,293,986	-1,488,126	-1,430,427	-1,457,679	-1,468,973	-1,494,243	-1,378,958	
1,266	1,266	1,266	1,266	1,266	1,266	1,266	

9.4 SUMMARY

The results of the cost-effectiveness analysis using the two base cases showed that existing ANC dominates IPTp throughout in Base cases I and II, resulting in negative net costs that made it unnecessary to estimate the ICERs. The results of the sensitivity analysis revealed that change in discount rate from base case rate of 3% to 6%, then to 10% and finally to 16.4% leads to less than 5% increase in the net IPTp costs. On the other hand, changing drug price downwards resulted in decreases of 9% and 5% in net costs for Base cases I and II respectively. Changing the drug price upwards led to over 30% increase in the net costs for the two base cases. By reducing the number of doses from four to two, net costs decreased by over 30% for Base cases I and II. The introduction of Hb testing as part of the IPTp also led to over 500% increase in net costs for Base case I and 398% for Base case II. Changing the base wage rate from female wage rate to the various other methods led to mixed results. By using the opportunity cost approach using the average male and female wage rate, the net costs decreased by less than 10% for Base case I and II. On the other hand, applying the strict form of HCA resulted in a 185% increase in resource losses leading to 12% increase in net losses for Base case I. The corresponding changes in Base case II were 3% and 17% decreases. The changes are more pronounced in FCA (over 30% decrease) than for the rest of the methods. By reducing the number of OPD visits and ALoS; and referral costs by half, the net costs reduced by less than 5% for both base cases. The increase in the proportion of non-bednet users led to 46% increase in net costs. Changing the DALY parameters (discount rate, years lived with disability (YLD) and age at onset of anaemia) for Base case I led to the following decreases in DALYs averted 27% (3% -6%), 48% (3%-10%) and 64% (3%-16.4%) for Base case I. The change in years lived with disability by LBW babies and the age of onset of anaemia led to 1% and 10% increase in DALYs averted respectively. However, changes in DALY parameters did not affect DALYs averted in Base case II. Simultaneously changing prevalence and CFRs for multigravidae substantially increased DALYs averted (to 5,770 and 1,270 for Base cases I and II respectively). Finally, by assuming all pregnant women (primigravidae and multigravidae) receive IPTp instead of multigravidae only showed that IPTp dominates for both Base cases I and II. This conclusion remained the same regardless of the inclusion of indirect costs or the type of wage rate used.

CHAPTER 10: DISCUSSION

10.1 INTRODUCTION

This chapter discusses study results. It is divided into three main sections. Section 10.2 discusses the methodological limitations of the study, in terms of the issues surrounding the collection and analysis of cost and effectiveness data. Section 10.3 summarises the findings and 10.4 discusses them. Section 10.4 also makes comparisons between this study and other economic evaluations of malaria interventions in The Gambia and in other developing countries.

10.2 METHODOLOGICAL LIMITATIONS

The analysis of costs and effectiveness is based on the analytical framework presented in Figure 5.1, Chapter 5. The validity of the data collected using the sub-components of the framework are discussed in this section. Overall, despite all the shortcomings, every effort was made to detect errors and to test all key uncertain variables.

10.2.1 Costs

The cost data collected comprises both the IPTp and the treatment costs to the provider, patients and their families. The IPTp cost to the provider includes the capital cost, health sector staff cost, initial training cost for the staff involved in IPTp, health promotion cost, drugs cost and the cost of other consumables used in the trial. However, it is worth noting that IPTp is an addition to the normal antenatal care. As a result, the additional cost of capital at the various antenatal health facilities was limited. The treatment of LBW and anaemia is done at the hospital level. The sample sizes used to collect cost data were 884 for the clinic questionnaire, 662 for the follow-up questionnaire, eight for the hospital observation study for VLBW, four for ELBW, 66 for OPD anaemia at AFPRCH, 20 for IPD anaemia at AFPRCH, 15 for anaemia at RVTH, 45 for the household time use study and 40 each for the male and female employment surveys.

The data collection process was not without its problems. One issue that presented difficulties in the fieldwork was that the three fieldworkers who were originally trained to administer the study instruments, were transferred to another trial and this necessitated their replacement. The change delayed the fieldwork because the new fieldworkers had to be trained again on the administration of the instruments. There were also problems with follow-up into neighbouring Senegal for those women who were residents of that country but usually came to The Gambia for their antenatal care. This was mainly due to the civil war in the Southern Cassamance region of Senegal.

The solution found was to have guarantors for those whose nationalities were in doubt. A 'guarantor' is usually a well-known woman (i.e. Traditional Birth Attendant) within the community who can attest to the nationality of the woman and be prepared to be held responsible if the woman was found to be non-Gambian. This approach helped in reducing the number of non-Gambian residents taking part in the trial to a manageable number.

The data for estimating the staff cost were collected through the observation method by the fieldworkers and so relied on their accurate recording of time. The data required to estimate the capital cost items used in IPTp, such as initial training and IEC, were obtained from the existing prices for workshops, radio and TV announcements and therefore the costs are reliable only in the short term. A discount rate of 3% was used for easy comparison with the results of studies in other settings. The time taken to see one woman for her first visit to the antenatal clinic was estimated using the observation method and subsequent visit times were obtained from the literature (Goodman et al, 2000). The DHT and DoSH staff supervisory times were observed only during the first visit to the health facility and there was no assurance that the time did not vary between visits. With enough resources, these could have been improved by observing women in all four visits to the health facilities required for IPTp.

In order to obtain the unit cost per multigravidae, the proportion of primigravidae to multigravidae was estimated using the antenatal statistics from the ESU, which revealed a ratio of 3:1. This ratio was used to project the year 2001 multigravidae population to 2003 in the two study areas in order to generate up-to-date sample sizes for Base cases I and II. Furthermore, projecting the total population of pregnant women to 2003 took care of any potential problems of economies of scale. While the estimated projection is consistent with other reports (Aikins, 1995), the proportion of those pregnant women who do not use bednets (22%) is contradicted by other reports in the same area, such as the Malaria control Unit (61.4%) and Meek et al (2001) (14%). The implication for this study is that, the result will depend on the proportion of non-bednet use, which in turn affects effectiveness, costs, consequences and cost-effectiveness of IPTp. Two studies conducted in Kenya and The Gambia showed that using different ITN coverage levels could lead to different cost-effectiveness levels (Goodman et al, 2000).

The unit cost for IPTp at health facilities was assumed uniform across facilities of similar category, which may not reflect the reality on the ground. The client flow study has already revealed that some facilities have longer waiting times than others (DoSH, 2000) which have cost implications for both the provider and patients. Furthermore, allocating the same supervisory time (DHT and DoSH supervisions) to health facilities of different sizes tends to overstate such time for smaller facilities.

The direct cost of IPTp was generated using clinic and follow-up questionnaires asking women to state how much they had spent on transport and/or at the clinic. There were problems with some of the responses because some women gave higher amounts than usual. The amounts included money they had spent on food for the household. Since most of the antenatal clinics are in comparatively bigger villages than their outlier villages, it is not unusual for women to take the opportunity of an antenatal clinic day to buy items such as rice, onions, tomatoes and other household needs, which they erroneously included as part of their expenditure at the clinic. The remedial action taken was to follow up those women who had given unusually high expenditures to further question them with a view to getting the correct amounts. Through this follow-up verification exercise, women were asked which items they spent money on during their health facility visits. Those who gave items such as a bag of rice, onions, cooking oil etc, had the costs of those deducted from the amounts they indicated. Although those detected were corrected, one cannot say for sure that all such errors were detected. However, since direct costs to patients are just a fraction of the IPTp costs (i.e. 6% for Base case I and 4% for II), this is unlikely to affect the findings of the study.

Indirect costs of IPTp — in terms of travelling, waiting and contact times at the health facilities — were obtained by two means. One asked the women to indicate time lost in terms of conventional time and the other used the rice-cooking time as a proxy. The former was obtained by linking the departure, travelling, and waiting times with local events such as early morning prayer time, breakfast, school times etc. In order to verify the results, especially given that the majority of the women did not have formal education (90%), rice-cooking time was used as an alternative measure of time. Contrary to expectations, the difference between the two methods (15 minutes) was significant at p-value of 0.00. The fact that the two are not the same means there could be an element of error. Most of the women do not normally read watches, so translating time into local events could minimise the error.

The average number of visits to antenatal clinics (n=3.5 times) in The Gambia was obtained from a published report (Telfer et al, 2002). However, it was realised that this figure is slightly different from the n = 3.4 visits reported by Cham (2003). Although the difference between these two may not affect the outcome of the study, the disparity should be noted. The indirect costs to families accompanying pregnant women to antenatal clinics was not included because only 2.5% were actually accompanied.

10.2.1.1 Treatment cost to the provider

Many challenges were faced in the collection of treatment costs to the provider. One problem with the payroll at AFPRCH was that only names and the salaries by department/unit and benefits were recorded while the staff designation was left out. The inventory of equipment was not available and so each item had to be physically counted, which was time consuming. Another problem with equipment was the difficulty in obtaining prices from catalogues. Data on drug usage and costs were one of the most difficult to obtain and so had to be estimated based on the updated figures from Bansang hospital (Fabricant & Newbrander, 1994).

Regarding outpatient care, the number of visits to hospital for anaemia treatment is based on the WHO and The Gambia DoSH treatment guidelines. However, the general tendency is that, as soon as the symptoms are cleared, most people stop visiting the health facilities and even stop taking their medication. Therefore, the maximum of four visits for outpatient anaemia treatment could be higher than what obtains in practice. Regarding inpatient care, the average length of stay (ALoS) for all non-fatal and fatal cases of VLBW, ELBW and anaemia were obtained from the hospital records corroborated by literature and expert advice. The ALoS for very severe anaemia at the RVTH was based on that of AFPRCH, but RVTH, being a teaching hospital, should have better equipment and specialist doctors, and therefore a shorter length of stay than AFPRCH for the same illness. A lower number of OPD visits would lead to a lower cost of an OPD visit to the provider, patients and families than estimated. On the other hand, assuming the ALoS at the AFPRCH to be the same as that of RVTH is likely to overstate the efficiency level and unit cost at the AFPRCH. Both cases above have ripple effects on the costs incurred by patients and families.

The hospital costing data for RVTH was obtained from previous studies, such as WHO (1995) and Fabricant and Newbrander (1994), and was updated using the Consumer Price Index (CPI). There have been a lot of improvements at the RVTH over the past 10 years. The improvements have however not been taken into consideration. Therefore, the unit costs of A & E, paediatrics and maternity wards could have been under-estimated. Due to the unavailability of data, the cost of drugs at the AFPRCH was based on the average drug usage at Bansang hospital. However, in reality, the average drug usage at the two hospitals may be different (Kirigia et al, 1998a), and so a tendency to overstate or understate the actual drug costs may exist. Nonetheless, a comparison of the unit costs of OPD, paediatrics and maternity wards at AFPRCH with that of RVTH shows that the two sets of data were very similar.

The AFPRCH cost analysis was based on the actual costs incurred at the various units of the hospital, obtained from the records. However, the state of such records at the AFPRCH left a lot to be desired, especially those relating to equipment and drug use. This paucity of data may have affected the accuracy of the unit costs of OPD and inpatient care. Another shortcoming worth noting is that the hospital cost analysis took all patients as homogeneous regardless of their differing state of morbidity. In fact, different patients have unequal use of resources such as drugs, tests and even staff time. In order to obtain the actual costs, weights should ideally be attached to patients in line with the severity of their illnesses, which will help differentiate costs amongst them. It is very common for the National Water and Electricity Corporation (NAWEC) generator at Farafenni to break down or fuel to run out, which affects the operations of the AFPRCH, causing delays in getting haemoglobin test results. The constant electricity failure has contributed to the high cost of fuel to run the hospital generator, which also has negative effects on both unit outpatient and inpatient costs.

Both the effectiveness and the treatment costs of LBW and anaemia depend on the underlying causes. For instance, LBW due to HIV, malnutrition or placental malaria may all differ in terms of treatment cost. Very severe and to some extent, severe anaemia would require blood transfusion as part of treatment. The real cost of treatment for anaemia depends on the underlying cause, severity and whether blood transfusion is needed or not. Blood transfusion has been recommended as the main treatment for very severe anaemia pregnant women (WHO, 1999). In the case of this study, the cost of blood transfusion has not been separately calculated but incorporated as part of the hospital costs in general, through the step-down process. Specifically, the cost of laboratory tests was stepped-down to all the wards including maternity. This could have underestimated the cost of treatment for the 42 and 4 very severe anaemia cases in Base case I and Base case II respectively. Therefore, the study findings should be viewed in that context. However, it may be unlikely that any adjustment would make a big difference in the conclusions.

AFPRCH has been operating at less than its full capacity, which has affected the unit OPD and inpatient costs. Even though it is one of the newest hospitals in the country, it lacks the basic staff and equipment to make it fully functional to provide quality care. The low utilisation could be a result of the poor quality of service at the facility, leading to high unit costs of both outpatient and inpatient care. Research has shown that increasing the availability of health services (for instance, by building more facilities or expanding health programmes) does not always increase the use of services (Thaddeus & Maine, 1994; p.1093).

10.2.1.2 Treatment cost to the patients and families

The information on the direct cost of treatment for anaemia and LBW to patients and their families was obtained from direct observation at the two hospitals (AFPRCH and RVTH). The accuracy of the information relied on the memory of the visitors in terms of the fares paid and the amount spent while at the hospital. Although the outliers were verified and where necessary corrected, there is no guarantee that all such errors were detected and corrected.

The direct costs of referral to patients and their escorts were assumed to be zero but due to the long distance from Farafenni to Banjul, it is possible for at least an escort to buy food or water while waiting for the ferry. In this study, there were no additional resources to survey the escorts of those referred to the RVTH.

The assumption that all the VLBW, ELBW and very severe anaemia cases seek prompt treatment at the hospital through peripheral health facilities may be exaggerated given that for many people in rural Gambia, as in most rural areas of Africa, the first-line treatment is a visit to traditional healers, or using drugs already at home, bought in a shop or from drug peddlers and pharmacies. The health facilities are usually the last resort for people to seek treatment after all other alternatives have failed (Ruebush et al, 1995; Ongore et al, 1989; Mensah, 2004). The figure for the proportion of severe anaemia cases who seek treatment at hospital level was obtained from the Safe Motherhood Costing Manual (WHO, 1999) which is a 'one-size fits all' tool with all the attendant disadvantages such as lack of generalisability to other settings. This was remedied by adapting this generic tool to the Gambian situation by combining it with local epidemiological data.

The indirect cost of treatment was estimated through the observation study at the hospitals (AFPRCH & RVTH) from the time women entered the hospital to the time they left. The data were tainted by lack of proper recording by two fieldworkers who were deliberately recording time without actually following the patients. This was detected after the first day and the fieldworkers concerned were dropped from the team and replaced by another pair. Although subsequent reviews and monitoring did not indicate that other fieldworkers committed the same error, it cannot be ruled out. The problem of electricity at AFPRCH caused serious delays in obtaining the results of blood tests for anaemic patients and affected the results of the time spent at the outpatient department. This can result in the understating or overstating of the waiting time. The travelling times for patients and their families for an OPD visit were obtained from patients and their escorts. However, the road quality varies throughout the year in both NBE and LRD, which could lead to travel times beyond the six-hour average reported for a round trip.

In terms of household time use data collection, only one week was used to collect data, so there is no certainty that the workload and pattern on one day, say Monday, of the surveyed week is the same for the rest of the other Mondays outside the survey week. By the same logic, only one week in a month and one season in a year were used and there is no guarantee that the week and the season are representative of all other periods. The study does not include the time use of male members of the household, which could have given insight into how household work is shared between couples in the study setting.

Both recall and observation methods were used to collect time use data for rainy and dry seasons respectively. The recall method relies on the women to accurately remember and for the fieldworkers to accurately record their daily activities and their times. The observation method could lead to unusual activities beyond what is normal without observation. Both of these could understate or overstate the results. The work periods and the corresponding remuneration for formal work (obtained through the employment survey) were obtained from official records and there was little doubt as to their accuracy. However, the pay rates for informal sector workers, such as maids, restaurant workers, taxi drivers, shepherds, etc, were not according to any written contract and so the study had to rely on the information given by the employees. In order to verify the authenticity of the data and thereby increase its reliability, employers were interviewed to obtain information on the payment, rest days and in-kind gifts their employees normally receive. Despite that, a tendency not to mention irregular gifts such as clothing and money given for health care is possible.

The estimation of indirect costs via unpaid work was based on the values of farming, income generating activities and unpaid household work. The household time use study clearly indicates that women in the study setting spent their time in a variety of ways, including productive and non-productive activities. A woman attending a clinic may take all the time from her social time, or all the time from her farming time, which have varying degrees of economic value. The fact is that not all of the time used at the work place is directed towards productive activities. Some of it is allocated to rest and other non-productive activities. Therefore, the value of the time used to attend health facilities for IPTp and to receive treatment could be higher or lower in reality. However, given the small amount of time that women spent on non-productive and household activities (i.e. community, socio-cultural and mass media activities together consumed only 0.801 minutes), this will not greatly affect the outcome of the study. In theory, given a well functioning labour market, women will allocate their time so that marginal benefit is equal to return to leisure equals return to paid employment. Due to rigidities, women may not, in reality, be able to allocate time in this way.

10.2.2 Health consequences

The two greatest methodological challenges were associated with the effectiveness of data. Although the accuracy of the data was outside the control of the candidate, the data provided raised many unexplained issues. The prevalence rate of LBW and anaemia for multigravidae was different from that of other studies (Greenwood et al, 1989; Morley et al, 1964; Shulman et al, 1996). Furthermore, there was no follow-up in the main trial to track LBW and anaemia patients at the hospital. This left no other option but to take the cost of all VLBW, ELBW and anaemia cases who sought treatment at the two hospitals during the data collection period (i.e. those in and outside the trial) in order to calculate the unit cost of treatment. There is the unlikely possibility that differences exist between the treatment costs of the participants in the trial and others outside it. Furthermore, mortality data were not collected alongside the trial, which compelled the candidate to gather secondary case fatality rates (CFR) from hospital records for 2003 and from personal communications with Dr. Osrin of the Institute of Child Health, University of London. The implication for this study is that the rates used may depend on the expert asked and may vary from person to person, thereby putting the accuracy of the opinions into question.

10.2.3 Costs, effectiveness and Cost-effectiveness

There are a few issues, which may affect the findings (costs, effectiveness and cost-effectiveness) of this study. From the point of view of cost-effectiveness of IPTp, both costs and effectiveness are likely to be affected by the seasonality of malaria in The Gambia as described in Chapter 1. The rainy season is usually the peak period for all types of malaria including malaria in pregnancy. Therefore, the benefits of IPTp are likely to be higher during this period than during the dry season. The period before harvest marks the hungry season in all communities in The Gambia which has an impact on not only anaemia but LBW as well. The hungry season comes to a height in September, when food from the previous year's harvest runs out, while the new harvest will not yet be available. Other seasonal causes of anaemia include the hookworm described in Chapter 3. The implication of the findings of this thesis is that the study averages the costs and effectiveness of the trial period (July 2002-February 2004), taking into account two rainy and two dry seasons. Furthermore, since the two seasons in The Gambia (dry and rainy) are of the same duration of six months, the averaging of the costs over one year automatically takes into account the seasonal effects. The only likely effect of seasonality is that attendance to antenatal clinics, which is the medium for IPTp delivery, is likely to reduce during the rainy season when women are very busy cultivating their fields. A preventive intervention such as IPTp may not represent a priority compared to daily survival activities.

10.3 SUMMARY OF KEY FINDINGS OF THE STUDY

The results of the study are summarised in Table 10.1. The total incremental IPTp implementation costs without indirect costs were D964,576 for Base case I. The costs of IPTp to the provider alone were D910,122, which comprises 58% of the IPTp costs for Base case I, while the rest was incurred by patients. The details of the composition of the costs was summarised in Section 6.5, Chapter 6. The main component of the recurrent cost to the provider was drugs (SP) (73%), followed by personnel costs (14%) for Base case I. The direct IPTp cost to patients and families comprises D54,453. When indirect costs are taken into account, the IPTp costs increased to D1,573,693. The indirect costs component of this was D609,117.

Table 10.1 Summary of major findings

	Base case I		Base case II	
	Direct costs	**Direct and indirect costs**	**Direct costs**	**Direct and indirect costs**
(1) IPTp IMPLEMENTATION COST				
Provider				
Recurrent	837,315	837,315	215,681	215,681
Capital	72,808	72,808	72,348	72,348
Sub-total	**910,122**	**910,122**	**288,030**	**288,030**
Patients				
Direct costs	54,453	54,453	11,983	11,983
Indirect costs	0	609,117	0	134,004
Sub-total	**54,453**	**663,570**	**11,983**	**145,987**
TOTAL IPTp IMPLEMENTATION COST	**964,576**	**1,573,693**	**300,013**	**434,016**
(2) RESOURCE SAVINGS				
Provider	-241,360	-241,360	-15,327	-15,327
Patients & families				
Direct	-15,835	-15,835	-592	-592
Indirect	0	-56,719	**0**	-3,684
Sub-total	**-15,835**	**-72,574**	**-592**	**-4,276**
TOTAL RESOURCE SAVINGS	**-257,195**	**-313,914**	**-15,920**	**-19,604**
Net IPTp implementation costs	**1,221,771**	**1,887,607**	**315,933**	**453,620**
(3) HEALTH CONSEQUENCES OF IPTp				
(i) Cases of LBW and anaemia averted				
Cases of LBW averted	-3	-3	0	0
Cases of anaemia averted (OPD)	-19	-19	1	1
Cases of anaemia averted (IPD)	-37	-37	-4	-4
(ii) Deaths from LBW and anaemia averted				
Deaths from LBW averted	0	0	0	0
Deaths from anaemia averted	-5	-5	0	0
((iii) DALYs averted				
DALYs from LBW averted	-0.69	-0.69	0	0
DALYs from anaemia averted	-125.15	-125.15	-0.13	-0.13
TOTAL DALYS	**-125.84**	**-125.84**	**-0.13**	**-0.13**

Source: Tables 8.6-8.14; Tables 9.1-9.4.

The total incremental IPTp implementation costs without indirect costs were D300,013 for Base case II. The costs of IPTp to the provider alone remained at D910,122, which comprises 66% of the IPTp costs for Base case II, while the rest was incurred by patients. The details of the composition of the costs was summarised in Section 6.5, Chapter 6. The main component of the recurrent cost to the provider was drugs (SP) (51%), followed by vehicle maintenance (14%) for Base case II. The direct IPTp cost to patients and families came up to D11,983. When indirect costs were taken into account, the IPTp costs increased to D434,016. The indirect costs were D134,004.

In terms of out-of-pocket expenditure at the health facilities in NBE, an average of D3.20 per woman was spent at the base facilities against D2.40 at the outreach facilities. Most of the expenditure in NBE was made at base facilities. In LRD, average out-of-pocket expenditure was D4.70 at base facilities and D2.20 at outreach clinics. In this case also, the highest expenditure was at base facilities. The highest number of those who paid for transport attended Soma Major Health Centre (n = 9) and then Farafenni MCH clinic (n = 4). Forty-seven per cent of the women spent money on food.

The measurement and valuation of indirect costs were important components of the economic evaluation of IPTp conducted in this thesis. Special household time use and employment surveys were conducted to obtain information on the pattern and value of unpaid work with a view to coming up with the hourly wage rate for women in the study setting. The main finding of the time use study was that an average of 12.7 hours per day was spent by women on various subsistence and household activities during the dry season. Amongst the activities, household work took the highest proportion with 6.4 hours per day. The highest number of hours for household work was on Wednesdays and Fridays with 7.1 hours and 7.5 hours, respectively, when women did not engage in farming. The higher the time use for farming, the lower for household work.

Time use also differed by settlement. Household work in the villages took 6.3 hours per day against 7.5 hours per day in rural towns. Household work was also the most time- consuming group of activities in NBE (5.9 hours per day) and LRD (seven hours per day). During the rainy season, household work decreased to four hours per day in favour of farming, which took precedence over all other activities during this period, with 8.7 hours per day. By combining the time for dry and rainy seasons, farming came out on top with an average time of 5.3 hours per day followed closely by household work with 5.2 hours per day.

The average wage range for women was D2.52-D15.45. The lowest represents the hourly pay rate for a health facility laundress/cleaner/orderly while the highest represents the rate for a market trader. The average pay rate for all other types of work performed by women was D5.75. The wage level for men varied from D1.62 - D8.75. The lowest represents the wage rate for a watchman and the highest is that of a shepherd. The average hourly pay rate across all forms of work performed by men in the study area was D3.83. The average hourly wage rates for women, men and for both men and women were D5.79, D3.83 and D4.77 respectively. The hourly wage rate for farming was D5.93, and was D15.45 for income-generating activities. In terms of ranking, the highest hourly wage was for the generalist in the replacement cost approach (RCA) (D5.98), followed by the average female wage in the opportunity cost approach (D5.79). Next was the specialist wage of RCA (D5.14), then average wages for males and females together (D4.77) and the wages of males alone (D3.83).

The health consequences of IPTp for Base case I showed three additional cases and no change in deaths for LBW. The corresponding values for anaemia were 56 additional cases and five extra deaths. The DALYs averted for Base case I were -125.84. For Base case II, no changes in cases and deaths were averted for LBW, and the corresponding numbers for anaemia were three additional cases and no change in deaths. The DALYs averted were -0.13.

The resource use consequences of the IPTp intervention showed that the provider, patients and their families incurred extra costs with IPTp. No savings were realised either by the provider or by patients or their families. This is because there were additional cases and deaths from both LBW and anaemia after the introduction of IPTp.

These losses in Base case I without indirect costs were -D241,360 to the provider, -D15,835 in direct costs to patients and their families leading to resource losses of -D257,195. When indirect costs were taken onboard, the resource losses came to -D313, 914. Out of this, indirect costs to patients and their families were -D56,719. When added to the direct costs, total loss of -D72,574 to patients and their families was incurred. In Base case II, the total loss, without indirect costs, came to -D15,920, broken down into -D15,327 as cost to the provider and -D592 as direct costs to patients and their families. The inclusion of indirect costs using the opportunity cost method of the female wage rate increased the losses to -D19,604. Indirect costs comprised -D4,276 and the rest constitute provider and direct resource losses.

Net implementation costs were D1,221,771 and D1,887,607 for Base case I with and without indirect costs respectively. The corresponding costs for Base case II were D315,933 and D453,620 for Base case II. These were calculated by summing the IPTp costs and resource losses. The inclusion of indirect costs thus increased net costs by 68% in Base case I and 44% in Base case II.

Sensitivity analysis revealed that costs and DALYs were sensitive to changes in drug prices, introduction of haemoglobin test, number of visits, method of measuring indirect costs and changes in effectiveness and case fatality rates. When sensitivity analysis was conducted by changing the prevalence and case fatality rates to the average prevalence and case fatality rates for primigravidae and multigravidae taken together, the results showed that IPTp dominates — more effective and less costly than the control — as illustrated by the magnitude of resources savings and DALYs averted compared to base case values. The savings due to giving IPTp to all pregnant women are far greater than the IPTp implementation costs. Dominance was also apparent in the sensitivity analysis with effectiveness parameter changes for multigravidae alone as shown in Table 9.9, though these results are given less weight here since the parameters were not derived from the trial.

10.4 DISCUSSIONS OF FINDINGS

The background of study subjects showed that the largest proportion of multigravidae falls within the age bracket of 20-29 years. This result is similar to a recent study conducted in North Bank Division, which shows the higher proportion of mothers of all gravidae within the same age bracket (DoSH, 2004). In line with the explanation in Chapter 4, Section 4.5, factors contributing to being multigravidae at a young age have a lot to do with cultural and traditional practices such as early marriage and lack of education and other opportunities for girls. The general belief, especially in rural areas, is that a woman's place is in the home. This means that, compared to boys, girls should be exposed to limited educational opportunities up to the time they get married. Madrassa education, which the majority of women undertake (81.2%), only exposes them to the basic principles of Islam which is the religion for 95% of Gambians. The lack of functional literacy of the majority of the rural women was responsible for the majority of them being involved in only household and subsistence work rather than formal work.

Understanding time was thought to be a major problem for rural women. To circumvent this, rice cooking was used as a proxy to measure time spent on major events of the day. The results revealed a significant difference between rice cooking as a proxy for measuring the time and relating conventional time to major daily activities (Section 7.5.2, Chapter 7).

10.4.1 Cost of IPTp

The unit cost of IPTp to the provider was D16.35 for Base case I, which comprised D15.04 as the unit recurrent cost and D1.31 as the unit capital cost. The corresponding costs for Base case II were D23.51, D17.61 and D5.91 respectively. The magnitude of the unit cost of IPTp was explained by the high recurrent costs relative to capital costs. The higher the number of women, the lower the cost of capital and the higher the recurrent cost. The relatively high recurrent cost-share stems from the use of incremental costing methodology on top of the existing ANC.

In the sensitivity analysis, the modest increases in costs from changing the discount rate was because capital cost represented only 8% and 25% of the incremental costs of IPTp for Base cases I and II respectively. The reason is that IPTp is an additional programme on top of the routine ANC and therefore does not require the use of large capital items such as buildings. Therefore, costs do not seem to be sensitive to changes in the discount rate for both Base cases I and II.

The recurrent cost component of IPTp comprised mainly drugs and personnel costs. Drug costs per woman were D12 and represented 73% and 51% for Base cases I and II respectively. The influence of changes in these costs on IPTp was shown in the sensitivity analysis. The main reason for the relatively high cost of drugs is because drugs such as SP in The Gambia are imported from developed countries and their costs are more or less dependent on the exchange rate of the Gambian Dalasi (money). The introduction of the haemoglobin test as part of IPTp in the sensitivity analysis led to a very substantial increase in IPTp costs by 520% for Base case I and 416% for Base case II. Haemoglobin testing is in theory part of routine antenatal care but in practice, it is only carried out in health facilities with laboratory services (WHO/DoSH, 2005).

The ideal way to cut down on costs is normally through economies of scale, by increasing the number of women and thereby decreasing the average costs. However, given the incremental nature of the IPTp cost, not much can be done to cut the unit capital cost which forms only 8% for Base case I and 25% for Base case II. The only way of controlling recurrent costs is to explore ways of cutting down on recurrent costs. This can be done through efficient use of resources by searching for cheaper sources of local drug supply instead of using foreign ones. The Gambian economy has experienced problems in recent years as explained in Chapter 4, Section 4.3, leading to a high foreign exchange rate and import prices. Drug prices used in the calculation were obtained from the Medical Research Council (MRC), which purchases most of its supplies from the United Kingdom where the strong Pound Sterling contributes to higher prices (i.e. equivalent of D12 per woman).

However, for the purpose of this trial, SP was imported from Cosmos Pharmaceuticals in Nairobi, Kenya, which is expected to be cheaper than supplies from U.K. Furthermore, supplies from the local wholesalers could be cheaper than the Kenyan source.

The importance of this drug cost (SP) may be because it was imported and the likelihood is that imported drugs are more expensive than those purchased locally. However, sensitivity analysis using local wholesalers as alternative sources of SP reduced the proportion of drug costs as part of recurrent cost only from 73% to 67% and from 51% to 44% for Base cases I and II respectively.

By virtue of IPTp being externally funded, the recipient country (The Gambia) has little or no choice as to where it is purchased. The recent case in point is that, the bulk of the malarial drugs used for the Global Fund Round V malarial programme in The Gambia were imported from outside the country. However, it is worth acknowledging that some of the local wholesalers were also allowed to supply limited quantities of the same drugs. Although a small step, the use of local suppliers represents a paradigm shift in policy, which if continued could be useful in reducing costs. The recent move by the United Kingdom government to untie donor funds is also a step in the right direction, which gives recipient countries a free hand to utilise donor funds.

On the other hand, the main catch is that, the IPTp programme in The Gambia could not succeed without external support because the government alone cannot shoulder the costs. Furthermore, with the policy of free antenatal services to all women, any attempt to introduce cost-recovery is likely to take a long time. Moreover, considering the very small average out-of-pocket expenditure (D0.98) made by women at the antenatal clinics, introduction of fees for IPTp could discourage usage. Previous funding studies in rural Gambia by Mills et al (1994) revealed that, household heads who usually bore health care bills for members of their households could afford a range of D1-D5 (i.e. average of D3). However, given the large household sizes and the polygamous environment of the study area, the likelihood of a household head paying for more than one pregnant woman at a time is high. This in turns means high financial burden on households.

For the drugs (SP), a combination of factors could contribute to reducing prices. The first, as already mentioned, is to look for cheaper suppliers, such as Egypt or the Netherlands, or through the WHO bulk purchase system directly from the manufacturers or to use local wholesalers.

Since the implementation is a public health concern that transcends beyond the research conducted by the MRC, the use of local suppliers to cut down on the high drug (SP) prices is a feasible option.

The patients' share of IPTp implementation costs for Base case I was D54,453, out of which direct costs comprised only 3.5%. The corresponding figures for Base case II were D11,983 and 2.8%. This shows that direct costs form a very small component of IPTp cost and are unlikely to adversely affect antenatal attendance in The Gambia.

The average fare paid by the few women who used paid transport to go to an antenatal clinic was less than D5. It is stipulated in the health policy that 75% of the population should be within a maximum radius of five kilometres to the nearest health facility (DoSH, 2001). It is evident that the bulk of those who paid fares and spent money at the health facilities attended facilities in base clinics, especially those in towns such as Farafenni and Soma. The women could have taken 'expensive trips' to seek antenatal care at this base clinic in order to use the opportunity to shop for the family, or it might be due to the general belief that better quality care was obtained at bigger health facilities rather than at the peripheral ones. Where potential patients have access to more than one facility, the tendency is to choose one based on their perception of the quality of care offered rather than distance (Iyun, 1994). The direct cost of IPTp at the outreach clinics is small; this could mainly be due to the short distance to travel to and from the clinic, which does not require payment of fares or spending money. On the other hand, it could be a result of lack of money to pay fares or spend at the clinic. It is also tempting to conclude that the majority of the women walk to the clinic because they live within a short distance of antenatal health facilities. However, this conclusion may not be entirely right as walking is not necessarily undertaken on a shorter travel distance. The low payment could be a result of lack of fares or means of transport within the locality. In such instances, the women would have no other option but to walk to health facilities.

One way of reducing the costs for women is to cut down on the long waiting time at the antenatal clinics. The waiting time at Gambian health facilities is unnecessarily long regardless of the method used to measure it. This has been attributed, amongst other reasons, to lack of staff and poor organisation of work at antenatal clinics on the part of the provider (DoSH, 2000). The Gambia enjoys a high antenatal attendance rate of 92% for the first visit only (WHO, 2006). The reason could be, women may not have problems in making first visits to antenatal clinics, but their commitment for subsistence and household works could make it difficult to honour subsequent visits to health facilities where waiting times are unnecessarily long.

Despite, the long waiting time, only 38.2% of women in the clinic exit survey described waiting time at the clinic as 'long', 52.1% were satisfied with the long wait, and only 25.4% were dissatisfied. The specific reasons for their satisfaction with long waiting times were not further explored. However, the fact that the majority of the women in the study area (90%) were illiterate, this could have made them shy away from criticising the waiting time in the open especially to those who actually administer the services. Some may feel that revealing their dissatisfaction with the method of delivery of antenatal services could lead to denial of such services in the future.

A similar study in South Africa revealed that women are not bothered by the waiting time because it usually accords them the chance to conduct business, knitting, sewing, weaving baskets and bagging food. The products are then sold to other women waiting for their turn (McCray, 2004) to be attended to. What is clear in The Gambia is that women have devised coping strategies for the long clinic waiting time. These strategies include sending their ANC card to the clinic the night before; turning up very early in the morning to be seen earlier; sending their ANC card in advance with another woman and then turning up later; or arriving at the end of the morning (DoSH, 2000).

Although childcare is an ongoing activity for women with young children, in rural communities, such a task is not seen as the responsibility of the mother alone but an activity happily shared by everyone in the household with spare time. Furthermore, childcare is seen as the main activity for able-bodied grandmothers and children below the marriage age. Given the high illiteracy rate of the girl child in rural Gambia, such people are not hard to find in the communities. In contrast to what obtains in The Gambia, in an environment where childcare is a problem, it could lead to low antenatal clinic attendance (McCray, 2004). From this study, childcare for mothers takes an average of 0.2 hours per day as an activity conducted on its own. This shows that childcare is usually shared in rural settings especially in polygamous families.

10.4.2 Resource use consequences

The resource-use consequences of the IPTp intervention showed that the provider made negative treatment cost savings. This negative savings (losses) are due to the negative effectiveness reported by the trial. In reality, if treatment costs are really saved, then such savings could be used to fund at least part of the implementation of the IPTp intervention. Moreover, household losses on treatment costs for Base case I were -D257,195 and -D313,914 without, and with indirect costs respectively. The corresponding losses for Base case II were -D15,933 and -D19,604.

Based on this evidence, it is not justified to give IPTp to multigravidae alone in The Gambia, regardless of whether indirect costs are taken onboard or not. This shows that, when only multigravidae are considered, very little is achieved in terms of treatment cost savings and efficient utilisation of scarce resources in preventing LBW and anaemia. By using prevalence and case fatality rates for multigravidae and primigravidae in sensitivity analysis, IPTp is justified (dominates). This is due to some savings made in treatment costs of LBW and anaemia and also from averting deaths from the two conditions. Since the treatment resource savings are higher than IPTp costs, investing in the IPTp intervention for all women saves resources for both the government and the household in treatment costs and in the process reduces infant and maternal deaths. Even without including indirect costs, resource savings in base cases were found to be higher than the IPTp implementation costs, leading to negative net costs. Moreover, the resource savings were increased further with the inclusion of indirect costs. The magnitude of resource savings varied with the wage rate used. When the base indirect costs wage rate was used (i.e. female wage rate), the resource saving was 20% above the direct cost only level. By using other wage rates, proportions of indirect costs fluctuate around this base rate from 9%-20%. The lowest represents the use of simple HCA and the highest, the replacement cost wage rate for generalist (D5.98). The rest of the wage rates produced proportions between this two. The corresponding proportion for Base case II was 23% and the range was 10%-23% for HCA and replacement cost approach for generalist respectively.

When IPTp was given to all pregnant women, the intervention was found to be cost saving, because IPTp was found to be both effective and less costly than the control. Another reason could be that IPTp is an incremental intervention to an already existing antenatal care, so the intervention cost is comparatively smaller to the likely resource savings from averting LBW and anaemia cases and deaths. Therefore, subtracting a larger cost-savings from smaller IPTp gives negative net costs. With DALYs averted being positive as indicated in Table 9.11A & B, the ICERs were negative. The effectiveness and case fatality rates for all types of LBW and anaemia from the trial were lower than those obtained from the literature. These might explain the high cases and deaths averted. The resultant cost savings realised outweighed the intervention costs, thereby leading to negative savings. In a nutshell, when IPTp was given to all pregnant women, it was found to dominate by being both less expensive and more effective than the control. Again in terms of funding therefore, it is advisable to invest in such interventions because they save resources which would otherwise be used for treatment of LBW and anaemia and avert the resources losses through deaths. The details are given in Section 9.3.7, Table 9.10.

10.4.3 Health consequences

The trial confirmed the earlier findings that IPTp was not effective for women who have at least one pregnancy in The Gambia (Greenwood et al, 1989; Greenwood et al, 1994a; 1994b). One reason could be that the trial might not have reflected the operational setting, and as such, trial participants could have been more likely to show high levels of compliance than those in 'programmatic settings' (Wiseman et al, 2003). The result could have also been different if LBW (1501-2449g), mild anaemia and parasitaemia cases had been considered. If ethics permitted, a more relaxed trial with fewer follow-ups could shed more light on effectiveness. The limited results of anaemia's contribution to the overall results as demonstrated in sensitivity analysis (Table 9.3) could be explained by two main reasons. First, the majority of those who suffer from anaemia fell within the mild or moderate categories. Therefore, using such categories to estimate DALYs led to fewer DALYs averted than it would have been with severe types of anaemia. This is because, the bulk of the women within the mild/moderate categories do not suffer from long-term disability let alone death.

In a country like The Gambia where 83% of the women are said to suffer from anaemia (NaNA/MRC, 2001), mild anaemia is very much part of daily life. One of the drawbacks of using DALYs in economic evaluation was already highlighted in Chapter 2, and relates to methodological issues of the DALYs. They did not help the answer obtained for this study because the disability weights attached to mild/moderate anaemia are very low compared to severe anaemia or LBW. Evidence from the WHO website on "age-specific disability weights for untreated and treated forms of sequelae" included in the *Global Burden of Disease* study showed that the disability weight attached to mild anaemia was zero before and after intervention. It was 0.011 before and 0.011-0.012 depending on the age bracket for moderate anaemia. These are negligible compared to disability weights of 0.291 before and 0.256 after intervention for all sequences of LBW (Murray, 1996). The other reason for the result is related to the shortcomings of using DALYs as a unit of measurement as it places more emphasis on deaths than on survival with disability. Therefore, the fact that fewer women die from anaemia means the contribution of anaemia to the total DALYs is less compared to LBW. Larger disability weights for anaemia might affect the cost-effectiveness result.

10.4.4 Incremental cost-effectiveness ratios (ICERs)

The CERs or ICERs of health interventions are crucial in advising policy in choosing between competing interventions (see Chapter 2, Section 2.2.1). Including resource savings in the comparison of the ICERs of the intervention is necessary in order for policy makers to ascertain whether the difference in resource savings changes the ranking (Picard et al, 1993).

When two interventions have similar ICERs from comparison of implementation costs and effectiveness, and varying resource savings, to save costs, the one with greater resource savings should be implemented (Picard et al, 1993). The results of this study indicate that IPTp for multigravidae is more expensive and less effective than routine antenatal care in The Gambia. Because the effectiveness rates of IPTp were in the negative, there was no point in estimating ICERs for the base case scenario (multigravidae only). The cost-effectiveness conclusion for the study remains the same regardless of the assumptions on indirect costs. ICERs were again not estimated for sensitivity analysis using the prevalence and case fatality rates for both primigravidae and multigravidae because IPTp was found to dominate. This situation has not changed whether indirect costs were used or not, and according to the method of measurement of indirect costs. However, the resource savings were higher with indirect costs than when they were excluded. The proportion of resource savings above the direct costs only level was 20% for Base case I. It was also found that the value of resource savings varied with the wage rate used. The resource savings for Base case I ranged from 9%-20% with the lowest representing the use of the simple (non-strict) form of HCA and the highest representing the replacement cost wage rate for a generalist (D5.98). The rest of the wage rates produced percentage of resource savings between these two values. The range for Base case II was 10%-23% with the lowest representing savings by using non-strict HCA and the highest the base wage and replacement costs for a generalist.

10.4.4.1 Methods of measuring indirect costs

A substantial component of women's time in rural Gambia is occupied by unpaid work. Due to the availability of farming implements, most of the men's work in rural areas is limited to four hours (8.00-12.00 am) or at most six hours per day, while women spend an average of 8.7 hours per day working during the rainy season. This study suggests that, using different methods to value indirect costs, especially in rural settings where formal employment is in limited supply, can lead to different results only in two cases, HCA and FCA in terms of effects on net costs or ICER. Other methods do not make much difference.

There is, in particular, some disparity between the values obtained using FCA and HCA. The values obtained in the base case analysis of multigravidae using the various methods are summarised in Table 10.2. While the former assigns zero value to unpaid household work, the estimates based on the Opportunity Cost and Replacement Cost approaches showed less variation in hourly rates of pay for women than both FCA and HCA. The zero value for unpaid work and negligible time spent on market work led to a lower value of indirect costs for FCA than for all other methods.

The straight interpretation of this is that all those who do not work in the formal sector have no productive value, which grossly understates the value of rural women who work for most part of each day. Furthermore, FCA is biased towards the skilled and well-to-do population where unemployment is almost non-existent, which raises equity questions (Koopmanschap, 1995).

The inclusion of indirect costs in economic evaluation does not make it perfect, as confirmed by the study results. A number of methodological issues have been exposed. These include the various assumptions about the value attached to time by individuals not in active work, the choice of wage rate, and the methods used to elicit the time given up (Jacobs and Fassbender, 1998). Contrary to suggestions that the opportunity cost method usually produces the highest values (Budlender, 2004), the results of this study have shown a different ranking, with the replacement cost method producing the highest value. The fact that the different methods have failed to produce the same value reinforces the view that the value obtained in measuring indirect costs largely depends on the method used. This implies that studies should openly state the method used in order to make comparison with others open and easier. As illustrated in Chapter 2, FCA is biased against unpaid work and biased in favour of labour in a formal work setting. HCA on the other hand tends to overstate indirect cost losses, which can change the ICERs (Koopmanshap and Rutten, 1994; Evers et al, 1997). The findings here are not different from those of Goeree et al (1999) who, in their valuation of productivity costs due to premature mortality, found that estimates from the HCA were 69% higher than when FCA was used.

The main question that arises from this is whether FCA and HCA are useful in subsistence settings where no formal work exists and the bulk of the potential workforce participants are engaged in unpaid work. In such settings, the issue of surplus labour is not relevant because everybody is busy doing their own work and a day missed in rain-fed agriculture could hardly be replaced. Therefore, instead of relying on FCA that undervalues indirect costs or HCA that overvalues them, perhaps there should be a third way where unpaid work is measured and the number of days away from work is based on epidemiological advice for any illness. The number of years of productive life lost due to death and productivity lost due to bereavement should be based on local values of the study setting rather than on conditions in the formal market.

MISSING

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costs using various indirect cost valuation methods

rtunity pproach le wage of D5.79	Opportunity cost approach (male wage rate) of D3.83	Opportunity cost approach (average wage rate for male & female) of D4.77	Replacement cost approach (specialist's maid wage rate) of D5.14	Replacement cost approach (generalist wage rate) of D5.98	Human capital approach (D2.43)	Frictional cost approach (zero wage rate)
	D	D	D	D	D	D
73,693	1,367,685	1,466,792	1,505,766	1,594,294	1,220,216	964,576
3,914	-295,117	-304,395	-308,079	-316,398	-286,643	-257,195
37,607	1,662,802	1,771,187	1,813,845	1,910,692	1,506,859	1,221,771
4,016	388,695	410,498	419,072	438,548	356,235	300,012
9,604	-18,390	-18,994	-19,234	-19,776	-17,488	-15,920
3,620	407,085	429,492	438,306	458,324	373,723	315,932

10.4.5 Comparisons with WHO threshold and other malaria intervention studies

The findings of this study revealed that the IPTp intervention for multigravidae is more expensive and less effective than routine ANC. This means that there is only limited value in comparing it with other cost-effective interventions. Therefore, attempts were made to compare it with only selected studies of malaria-control interventions in The Gambia and SSA using the list of cost-effectiveness studies compiled by Goodman et al (2000). The disparities in data between this study and those reported by Goodman et al (for 1995) were maintained because updating them to the 2003 values would not change the ranking. However, it should be noted that, as rightly put by Goodman et al (2000), the cost-effectiveness of each intervention depends on several factors, such as drug resistance and duration of transmission, which makes simple comparison of results difficult. In line with that view, the comparison here is meant to give only a broad and rough indication of the relative cost-effectiveness of IPTp and other interventions studied either in The Gambia or elsewhere in the developing world. Comparison is limited to malaria studies only, with an emphasis on those conducted in SSA.

10.4.5.1 Comparison with WHO threshold

The WHO threshold states that all interventions in low and middle income countries are considered 'very attractive' when cost per DALY averted or discounted life years gained (DLYG) is lower than the threshold value of $25, and 'attractive' when below the upper threshold value of $150 per DALY averted (WHO, 1996).

According to base case assumptions, ANC dominates. Therefore, this discussion focuses on the sensitivity analysis which used the average prevalence and case fatality rates for anaemia obtained from the trial and Shulman et al (1996; 1999) and also rates for LBW from the trial and Rogerson et al (2000) as proxy rates for all pregnant women (primigravidae and multigravidae). Since IPTp dominates the WHO threshold is irrelevant. For easy comparison with similar studies conducted elsewhere, findings were converted from Gambian Dalasi to a common denomination, the US Dollar, using the average end of year (2003) Gambian Dalasis (money) exchange rate of D28.7344 to 1 US Dollar. The results are indicated in Table 10.3.

No previous studies on the cost-effectiveness of SP as IPTp have shown dominance but they have all shown that it was cost-effective for primigravidae and the results of the sensitivity analysis using primigravidae and multigravidae in this case reinforced it. Thus, using the total pregnant woman population, trial costs, primigravidae effectiveness from the literature and multigravidae effectiveness from the trial, completely transformed the results.

Even though giving IPTp to multigravidae confers no benefit, health benefits for primigravidae outweigh the costs of treating all women. The analysis is in keeping with the one made by Goodman et al: which concluded that if all pregnant women receive IPTp, the effectiveness of IPTp for primigravidae will to some degree outweigh the limited effects on multigravidae, and the intervention remains cost-effective (Goodman et al, 2000). As already indicated in Chapter 8, giving IPTp to multigravidae led to more harm than good in terms of the extra number of deaths from and cases of both LBW and anaemia. This is true for both Base cases I and II. The ethical dilemma that one faces due to the trial finding is whether to give SP as IPTp to multigravidae in the Gambia after knowing that it confers no benefits. If anything, it carries some risks.

Table 10.3 Costs and consequences of giving IPTp to all pregnant women (US$) from sensitivity analysis

Costs in US$	Without indirect costs	With indirect costs	Sensitivity Analysis by changing the wage rates				
		Base case wage rate	Opportunity cost approach (male wage rate)	Opportunity cost approach (average wage rate)	Replacement cost approach (Specialist's maid wage rate)	Replacement cost approach (Generalist wage rate)	Human capital approach
	0	D5.79	D3.83	D4.77	D5.14	5.98	D2.43
Base case I (Women= 74236)							
Incremental IPTp cost							
IPTp cost	44,964	71,888	62,329	66,909	68,715	72,816	55,487
Resource savings	244,283	292,112	276,774	284,099	287,022	293,584	266,182
Net costs	**-199,319**	**-220,224**	**-214,445**	**-217,190**	**-218,307**	**-220,768**	**-210,696**
DALYs	**5,342**	**5,342**	**5,342**	**5,342**	**5,342**	**5,342**	**5,342**
Base case II (Women=16332)							
Incremental IPTp cost							
IPTp cost	12,763	18,981	16,878	17,886	18,283	19,185	15,373
Resource savings	57,776	70,751	66,640	68,596	69,386	71,168	63,343
Net costs	**-45,013**	**-51,770**	**-49,762**	**-50,710**	**-51,103**	**-51,983**	**-47,970**
DALYs	**1,266**	**1,266**	**1,266**	**1,266**	**1,266**	**1,266**	**1,266**

10.4.5.2 Comparison with malaria-control studies in The Gambia

Since there has been no previous IPTp study in The Gambia, comparisons were done with similar cost-effectiveness studies of malaria-control interventions in The Gambia. These were to do with chemoprophylaxis for children (Picard et al, 1992), insecticide treatment of bednets (Picard et al, 1993), and modelling to estimate cost-effectiveness of net treatment (Graves, 1998). The details of the results of these studies are in Table 10.4. No intervention was shown to be dominant.

The only study that estimated the net CER was by Aikins et al (1998), which showed the net cost per child death averted as $494 and the cost per DALY averted as $21. In terms of cost per DALYs, the range was $9-$27, where the lowest represented the cost per DALY averted due to insecticide treatment of bednets (Picard et al, 1993) and the highest was the gross cost per DALY averted due to insecticide treatment of bednets (Aikins et al, 1998). As with the base case, the results of the sensitivity analysis using the prevalence and case fatality rates for all pregnant women (primigravidae and multigravidae) cannot be directly compared with those of previous studies in the same settings because IPTp completely dominates.

Table 10.4 Cost-effectiveness studies in the Gambia (in 1995 US$)

Reference	Type of intervention	Cost per case averted	Cost per death averted	Cost per DALY averted or DYLG
Picard et al., 1992 (1988 data)	Chemoprophylaxis for children	-	$167	-
Picard et al., 1993 (1989-90 data)	Insecticide treatment of bednets	-	$219 (167-$243)	9(9-$14)
Picard et al., 1993 (1989-90 data)	Insecticide treatment of bednets and chemoprophylaxis	-	$300 ($246-$333)	$13 ($13-$20)
Aikins et al, 1998 (1991-92 data)	Insecticide treatment of bednets	-	Net CER $494 ($326-805)	$21 ($14-$35)
Aikins et al, 1998 (1991-92 data)	Insecticide treatment of bednets	-	Gross cost $665	Gross $27
Graves, 1998	Insecticide treatment of bednets	-	$829 ($447-2117)	-

Source: Goodman et al (1999a)

10.4.5.3 Comparison with IPTp in Sub-Saharan Africa (SSA)

The results of this study were also compared to other malaria control interventions conducted in SSA in terms of cost per case, death or DALY averted, as illustrated in Chapter 3, Table 3.3. No study showed dominance. The cost per case averted ranged from $1.20-$113, where the lowest is the cost per compliant woman to chemoprophylaxis with coated chloroquine and old health education (Helitz-Allen et al, 1993) and the highest being the cost per case averted for antenatal treatment with chemoprophylaxis using weekly doses of chloroquine (Schultz et al, 1995). It is also worth mentioning here that none of the alternative studies considered indirect costs in their economic evaluation, and so comparing their results with those obtained from this study is not exactly comparing like with like. The range of cost-effectiveness ratios in terms of cost per death averted was $18-$542. The lowest represented the cost per death averted from antenatal treatment with chemoprophylaxis in Malawi (Schultz et al, 1996) and the highest, the cost per death averted using doses of chloroquine followed by weekly chloroquine in Malawi (Schultz et al, 1996). As stated in Chapter 3, Table 3.3, most of these studies considered only drug prices and adopted the provider perspective (Heymann et al, 1990; Helitzer-Allen et al, 1993; Schultz et al, 1995; Schultz et al, 1996; Goodman et al, 1999b; Wolfe et al, 2001). Similar outcomes were realised for cost per DALY averted. In terms of cost per DALY averted, only one estimate was given; $4-$29 (Goodman et al, 1999b). A recent study by Berman et al (2006) indicated that IPTp with SP including additional doses for HIV positive women showed the ICER at $13 per DALY averted. The results of this study (sensitivity analysis) could not also be compared with the results of similar studies in SSA because in the base case, the control dominated and in the sensitivity analysis IPTp dominated. However, resource savings for Base cases I and II obtained from the sensitivity analysis using all pregnant women showed that the magnitude of savings was higher when indirect costs were included. The level of resource savings was also found to have varied depending on the wage rate used. In both Base cases, DALYs averted were higher in IPTp than in the control.

Table 10.5 Cost-effectiveness studies in Sub-Saharan Africa and selected developing countries (in 1995 US$)

Reference	Area studied	Type of intervention	Cost per case averted	Cost per death averted	Cost per DALY averted or DYLG
Sub-Saharan Africa					
Goodman et al, 1999	Sub-Saharan Africa	Chemoprophylaxis for children	-	-	3-41
Goodman et al., 1999	Sub-Saharan Africa	Insecticide treatment of bednets	-	-	4-10
Binka et al, 1997	Ghana	Provision and treatment of bednets	-	2112 (992-2289)	77 (37-84)
Some, 1995	Kenya	Provision and treatment of bednets	-	2958 (2838-3120)	-
Evans et al , 1997	Africa	Provision and treatment of bednets	-	-	10-118
Goodman et al, 1999	SSA	Provision and treatment of bednets	-	-	19-85
Goodman et al, 1999	SSA	Residual spraying	-	-	16-58
Utzinger et al, 2001	Zambia (1929-1950)	Environmental management with DDT residual spraying in later years	-	858	22-591
Sudre et al, 1992	Africa,1991 (drug costs only)	Drug treatment for children with CQ	-	-	-
		No resistance	-	1.47 (0.21-3.36)	-
		Low Resistance	-	1.49 (0.22-3.36)	-
		High Resistance	-	2.56 (0.31-4.34)	-
Sudre et al, 1992		Drug treatment for children with AQ	-		-
		No and low resistance scenarios	-	2.35 (0.34-5.40)	-
		High resistance scenario	-	2.89 (0.40-5.67)	-
Sudre et al, 1992		Drug treatment with SP	-		-
		All resistance scenarios	-	1.70 (0.25-3.92)	-
Goodman et al, 1999	Sub-Saharan Africa	Improving compliance	-		2-8
Goodman et al, 1999	Sub-Saharan Africa	Improving access to second and third line drugs	-		1-3
Wiseman et al, 2003	Kenya	Insecticide treatment of bednets	38-49	1,214	Net CER* 25-34
Other Developing Countries					
Akhavan et al, 1999	Brazil	Residual spraying, fogging and source reduction	-	5072(785-10,427)	132
Akhavan et al, 1999	Brazil	Residual spraying, fogging and source reduction, and a package of measures placing greater emphasis on early diagnosis and prompt treatment	-	2596 (1093-5193)	67
Akhavan et al, 1999	Brazil	Package of measures to place greater emphasis on early diagnosis and prompt treatment	-	677 (271-1355	17
Mills, 1993	Nepal	Case detection and treatment, and residual spraying	-	Net CER* 109-17,650	Net CER* 12-1803

Source: Goodman et al (1999). * Net CER incorporate potential cost savings to government and household from reducing malaria incidence.

10.4.5.4 Comparison with malaria control studies in developing countries

The final comparison was made with selected malaria control programmes conducted in other developing countries (Table 10.5). In this case also, no studies showed dominance, and only two studies are directly comparable in terms of their estimation of the net cost-effectiveness ratios. These are case detection, treatment and residual spraying in Nepal (Mills, 1993) and insecticide treatment of bednets in rural Tanzania (Wiseman et al, 2003). As indicated in Table 10.5, the cost per death averted was $109-$17,650 (Wiseman et al, 2003) and cost per discounted years of life gained (DYLG) was $12-$1,803 (Mills, 1993). The net cost per case averted was $38-$49, net cost per death averted was $1,214 and net cost per DYLG averted was $25-$434 (Wiseman et al, 2003). The results of the two base cases (I and II) reported in this study by using the prevalence and case fatality rates for all pregnant women (primigravidae and multigravidae), are more attractive than the ranges of each of these two studies in terms of cost per DALY averted.

In terms of cost per death averted for all other studies, the range was $1.47-$2,958. The lowest represents the malaria treatment options with chloroquine and non-resistance in Africa (Sudre et al, 1992) and the highest represents the cost per death averted in Kenya through the provision and insecticide treatment of bednets (Some, 1995). For the rest of the other studies, the least attractive cost per DALY averted reported was $77 (Binka et al, 1997) for the provision and insecticide treatment of bednets for children in Ghana. Base cases I and II in the sensitivity analysis using all pregnant women (primigravidae and multigravidae) (Table 10.3) reported here are more attractive than the results of Binka et al.

10.5 CONCLUSION

In conclusion therefore, one can safely state that the control (ANC) dominates in this study if IPTp is provided to multigravidae only. On the other hand, the sensitivity analysis using the prevalence and case fatality rates of the trial for multigravidae and those reported for primigravidae showed that IPTp dominates compared to control. Inclusion of the resource savings meant that IPTp was actually cost saving because the resource savings were greater than the implementation costs and DALYs were averted. Therefore, giving IPTp to all pregnant women would save lives and productive time for the beneficiaries.

CHAPTER 11: CONCLUSIONS, POLICY IMPLICATIONS AND PRIORITIES FOR FUTURE RESEARCH

11.1 INTRODUCTION

The last chapter of this thesis presents the conclusions, policy recommendations of the study and outlines areas for future research. The chapter is arranged in three main sections. Section 11.2 discusses how the study objectives were fulfilled and the contribution of the research to knowledge; Section 11.3 presents the implications of the study findings for policy; and Section 11.4 outlines possible areas for future research.

11.2 FULFILMENT OF STUDY OBJECTIVES AND CONTRIBUTION OF THE RESEARCH TO KNOWLEDGE

11.2.1 Fulfilment of research objectives

The study estimates the cost-effectiveness of introducing IPTp to multigravidae pregnant Gambian women and explores the effect of different approaches to measurement and evaluation of indirect costs on the ICERs. To achieve this aim, the study sets out three objectives, which needed to be fulfilled. Quantitative methods were used to collect the costs and effectiveness data to estimate the cost-effectiveness of the IPTp. The details of the research objectives and the methods used to achieve them, as outlined in Chapters 1 and 5, are to:

1. Examine the cost-effectiveness of introducing SP as IPTp for malaria into normal antenatal care for multigravidae women in rural Gambia;
2. Explore various methods of valuing indirect costs and assess the extent to which they affect the cost-effectiveness ratio and
3. Make policy recommendations as to whether to introduce SP as IPTp on cost-effectiveness grounds.

Therefore, the main purpose of this section is to assess whether the research conducted succeeded in achieving the objectives of the thesis. Objective three is the subject of Section 11.3 of this Chapter 11 and it focuses on the provision of policy recommendations. Therefore, the focus of this section is to present answers to objectives one and two only.

Objective one involved determining the incremental cost of IPTp at the various health facilities by collecting cost data for the health care provider and women enrolled in IPTp trial as well as the effectiveness of the IPTp. The cost to the provider presented in Chapter 6 was estimated in terms of the additional staff time, DHT and DoSH supervisory time and the cost of drugs (SP) specifically required for the IPTp.

Limited capital costs, which included the IEC and initial training of staff who administered IPTp, were included. The results have been presented in terms of recurrent and capital costs and by health division.

The costs to patients included both direct and indirect costs. These were collected through clinic exit questionnaires. These were administered at all the antenatal clinics on the first enrolment of the women, complemented by the use of observational studies and estimates from health workers. The results for the direct cost of IPTp to patients were presented in Chapters 6 and the indirect costs in Chapter 7.

The study of the treatment cost of LBW and anaemia cases treated at the hospital level was conducted at AFPRCH and RVTH. A hospital costing study was conducted at the former, while the costs for the latter were obtained from previous studies and updated to 2003 values, using the consumer price index. The cost of treatment to the provider included referral costs from peripheral health facilities to AFPRCH and where applicable, to the RVTH. It also included OPD and inpatient costs. The results of the provider costs of treating LBW and anaemia were presented in Chapter 6.

In terms of costs to patients, observation studies were conducted at each of the hospitals with a view to obtaining both direct and indirect costs of treatment for LBW and anaemia incurred by patients, their escorts and family members. The indirect costs of treatment were presented in Chapter 7, while direct costs were presented in part of Chapter 6.

The effectiveness of the IPTp intervention were estimated and presented in terms of cases of LBW (VLBW and ELBW) and anaemia (moderate, severe and very severe) averted, deaths from LBW and anaemia averted, and DALYs averted. The resource use consequences of IPTp in terms of savings to the health care provider as well as to patients and their families were also estimated in Chapter 8. To arrive at the ICERs, all the results in Chapters 6 to 8 were pulled together to estimate costs and resource savings and, net costs for the IPTp intervention for Base cases I and II. Specifically, the cases, deaths and DALYs averted as well as resource savings estimated in Chapter 8 were combined with the IPTp and treatment costs estimated in Chapter 8, and indirect costs from Chapter 7, to attempt to estimate the ICERs in Chapter 9.

To address objective two, exploring various methods of valuing indirect costs and assess the extent to which they affected the cost-effectiveness ratio; the study used a time use and an employment survey.

The results of these were combined to estimate the hourly wage rate for unpaid work using the opportunity cost approach (female wage rate) as the base case and opportunity cost approach (average of female and male and male wage rates), the replacement cost approach, the human capital approach and the frictional cost approach in sensitivity analysis. The results of the valuation are presented in Chapter 7.

11.2.2 Contribution to Knowledge

This research is designed to contribute to the long-standing problem of malaria in pregnancy through economic evaluation of IPTp, and to contribute to enhancing knowledge in a number of ways.

Previous studies on CEA of IPTp were conducted from the perspective of the health care provider whereby only costs related to the health care provider were taken into account. Most of the other studies of malaria prevention in developing countries that estimate cost-effectiveness did not take into account patient and family costs. For the few that included such costs, they were limited to direct out-of-pocket costs while indirect costs were excluded. Moreover, where indirect costs were included, they traditionally emphasised losses from paid work over losses from household work. The emphasis of this thesis is different in that respect because it went beyond the usual provider to a societal perspective by also incorporating direct and indirect costs related to patients and their families.

The study also contributes to knowledge in the sense that there is no known cost-effectiveness analysis of IPTp for multigravidae. In fact, one can safely state that this is the first study that estimates the cost-effectiveness of IPTp for multigravidae. The study went beyond considering only primigravidae, secundgravidae or all pregnant women but rather focused on multigravidae as a specific group.

The study used different data collection methods and tested different approaches to valuing indirect costs. It provides baseline data on indirect costs in rural Gambia by using household time use methods through a combination of recall, observation and diary methods to measure time. Previous time use studies have been limited to measuring time by using either observation or recall methods.

Estimating indirect costs involved both time measurement and valuation. However, most studies measured time and then used secondary data in the form of wage rates to value them. For this study, an employment survey was used to value women's time. Furthermore, the study went beyond using the paid wage within the formal labour market in the form of the minimum wage (which does not exist in The Gambia), or the male wage rate (which happens to be lower than the ones estimated for women), average or constant wages.

Empirically, there is little exploration of the implications of including indirect costs or different ways of measuring indirect costs in cost-effectiveness estimates of malaria prevention. This is one of the few studies that place emphasis on indirect costs especially unpaid household work. It explores not only the effects of including indirect costs but specifically uses different methods of measuring and valuing indirect costs, critically appraises these methods and examines their impact on cost-effectiveness estimates. It contributes to time costing research by highlighting discrepancies that could occur as a result of using different methods and therefore reaching different policy conclusions. However, it also showed that different approaches of the same method (HCA) led to minimal changes in the conclusion.

The findings reveal a lot about conducting economic evaluation alongside a clinical trial. It is tempting to state that the risk of having negative results like in this study means it would be better for economists to wait to get efficacy results before conducting a CEA of this nature. However, in reality, the results of clinical trials can turn either way. Therefore, results like these should not deter economists from conducting CEA alongside clinical trials. It is better to accept that clinical and economic studies need to be done together, and that inevitably, certain interventions will be found not worth conducting the trial (more expensive and less effective). The sensitivity analysis demonstrates the value of exploring sensitiveness and an important finding was that, unlike the trial results for multigravidae, which showed that the control (ANC) dominates, giving IPTp to all pregnant women showed that IPTp dominates.

11.3 IMPLICATIONS OF THE FINDINGS OF THE THESIS ON POLICY IN GAMBIA AND ELSEWHERE

The IPTp trial did not establish that IPTp of multigravidae was cost-effective because the Control dominates. On the other hand, by giving IPTp to all women (e.g. primigravidae and multigravidae), IPTp was found to have dominated. The policy implications of these findings, as in the case of the main study, are not very clear. The implications of the findings of this study revolve around the question of whether it is managerially a good idea to target IPTp on primigravidae or to give it to all pregnant women, even if multigravidae do not necessarily benefit from it because it is cost saving.

The cost of treating LBW and anaemia and averting deaths from the two conditions was found to be far more than the IPTp intervention costs. This can be argued in two ways. The first is to give IPTp to all pregnant women based on managerial convenience and the real life experience of the researcher in the field.

One of the difficulties that may arise in excluding multigravidae is that an ordinary rural woman may not understand the rationale for leaving her out from apparently benefiting from malaria prevention. "What about me?" was a question frequently asked during the time of the IPTp trial by several women wanting to be recruited. Some of those enrolled sometimes brought along their friends to be also considered for enrolment. This shows the difficulties involved in excluding women from preventive care such as IPTp.

It will be difficult to explain to such women that their friends or relatives are not entitled to be on IPTp on efficacy and therefore cost-effectiveness grounds. Goodman et al (2000) argues that 'the complexity of offering different services to different groups of women, and the political implications of excluding some women from valuable services like health, make it necessary to follow the Kenyan example and offer IPTp to all women'. The findings of the sensitivity analysis show that results change from positive for primigravidae (in the literature), to negative for multigravidae in both Base cases I and II. However, the results of the sensitivity analyses for all pregnant women (primigravidae and multigravidae) found IPTp to dominate.

Another important issue to consider is that, being the only study that involves multigravidae, the trial was not the last word on effectiveness, as it could be flawed, in which case it would be sensible to conduct further studies. Since there have been no other known studies that used SP for multigravidae, and considering the shortcomings of this trial as explained throughout the thesis, further studies are worth conducting in order to establish conclusive information on the effectiveness of IPTp to multigravidae. On the other hand, one could conclude that administering IPTp to all women could be regarded as waste of scarce health resources, which could otherwise be used for other urgent health needs. This remains so despite the fact that SP is a cheap drug, which is less likely to put serious constraints on health resources. More serious evidence against giving SP to all pregnant women is that it causes harm to multigravidae in terms of additional deaths and cases of both LBW and anaemia. Therefore, in the light of the two opposing arguments, one tends to question whether managerial convenience or political correctness are more pressing than the likely harm to be caused by giving IPTp to all pregnant women.

In conclusion, based on the evidence provided in terms of efficacy, costs, and cost-effectiveness, it is suggested that the DoSH should limit the implementation of IPTp to primigravidae only until clear advice is available on its effectiveness status for multigravidae.

It has been demonstrated in the sensitivity analysis that reducing implementation costs is important. A way of controlling the cost is to limit the number of SP doses per woman to only two, as recommended by the WHO. This ensures both the provider and patients save on the cost of the extra two visits. The reason for reducing the doses is that the HIV prevalence rate in The Gambia is 1.1% for HIV 1 and 0.6% for HIV 2 (DoSH Sentinel Bulletin, 2005). These rates are less than the 5% or 10% benchmark necessary to justify more than two doses of IPTp (Steketee et al, 1996a; Wolfe et al, 2001).

The results of the study reveal that the use of bednets has a direct relationship to the effectiveness of IPTp. The study found protection at a significant level against LBW and anaemia for those women enrolled in the trial but who do not sleep under bednets at home. It was demonstrated that although IPTp has not been effective for the entire multigravidae population, it has been found to be effective for those multigravidae who do not sleep under bednets. In that case, the finding may be useful to The Gambia, but more so to countries where bednet use is very low. Given the results of the study, ITNs appear to have positive effects because all those women who slept under bednets are less affected by IPTp compared to those who do not use bednets. Therefore, ITNs appear to be a good substitute for IPTp. In the light of this finding, efforts need to be intensified to advocate the use of ITNs through Information, Education, and Communication (IEC) and provide ITNs to improve prevention, which can help reduce malaria in pregnancy as well as LBW and anaemia. The enthusiasm shown by UNICEF, WHO and other multi-lateral agencies in malaria prevention and control, could be tapped so that there are resources to provide IPTp to primigravidae and to fund treatment of bednets for multigravidae who are not on IPTp.

The research findings on indirect costs give prominence to unpaid work largely performed by unskilled women. Gender inequality has been in the limelight for decades without much success in redressing the issue. Perhaps using health as an entry point will help address some of the problems women face in subsistence settings. One such problem is the exclusive responsibility of women for household work and taking care of the sick in such settings. By recognising and taking positive steps to alleviate the burden brought about by the multiple roles of women, it will not only have an impact on their health, but their lives as well.

The results in Chapter 7 show that women in rural Gambia work an average of 12.7 hours per day during the dry season on all activities including household work. However, household work tends to increase on Wednesdays and Fridays (7.1 hours and 7.5 hours respectively) when women do not normally work in the farms or rice fields. Household work on all other days accounts for 6.4 hours. The average time for farm work during the rainy season is 8.7 hours while the rest (4 hours) is spent on household work.

The findings from this study underscore the fact that malaria in pregnancy is a serious burden to pregnant women, their families and the infants. This is indicated by the indirect costs incurred in its treatment, which justify efforts to combat the disease through effective prevention and control. Out of total treatment costs for LBW and anaemia, including those incurred by providers, 18% was due to indirect costs. From the total treatment costs incurred by patients and their families alone, indirect costs represent 78% for Base case I. In the case of Base case II, indirect costs represent 19% of the total treatment costs and 86% of the treatment costs incurred by patients and their families. These show that indirect costs are a key component of treatment costs for LBW and anaemia in rural Gambia.

Although over half of the women considered waiting times at the antenatal clinics 'normal', the fact that they have devised coping strategies means it is indeed a problem. Efforts need to be made to reduce the long waiting times at health facilities especially during the rainy season when most women are busy at their farms. This can be done by improving the health care delivery at antenatal clinics thereby enhancing the quality of health services to the rural population.

The study offers a good opportunity to improve certain aspects of antenatal care delivery in The Gambia. The relevance, as well as the significance of the measurement of indirect costs, might influence decisions on the expansion of health facilities by giving due consideration to more efficient methods of delivering health care to improve antenatal attendance. Therefore, antenatal clinic days at the outreach facilities in the village, especially during the rainy season, should as much as possible be scheduled in close consultation with the community (women). Ideal clinic days could be Wednesdays and Fridays when most of the rural women do not go to their farms. This will reduce the conflict between health seeking behaviour and unpaid work necessary for the survival of the rural women and their families.

11.4 RECOMMENDATIONS FOR FUTURE RESEARCH

Despite the efforts to conduct cost-effectiveness analysis of IPTp for multigravidae, and to explore the issue of indirect costs, a few outstanding areas require future investigation. Unpaid work was estimated for only one person in the household, i.e. the woman. It could have been interesting to see how unpaid work is distributed at the household level between men, women and children, and its effect on health seeking behaviour. Since IPTp involves both infants and mothers, future research could assess the effect of LBW on schooling for children. The sample size for the household time use study can in future studies be increased and the data collection done for rainy and dry seasons through the observation method over a longer period (e.g. 2-3 months per season) instead of one week, with a combination of observation and recall methods. Instead of using the hospital costing results, specific costs relating to the treatment of LBW and anaemia can be taken and the results contrasted with the values obtained for the general hospital costing. In addition, hospital cost analysis can in future be done on a larger number of patients conducted over a longer period, say one year, in order to factor in the outliers in terms of seasonal variation of malaria in pregnancy, LBW and anaemia. That, rather than the 21-day period used for this study, would lead to more accurate cost estimates. It will also be informative to policymakers when the scope of costing is expanded to include the lifetime cost long-term costs of both LBW and anaemia.

The Riders for Health (RFH) contract has many positive aspects in terms of DoSH vehicle fleet management. It has specifically reduced the arbitrary use of health vehicles and in the process cut down some of the avoidable repair costs. The DoSH should find ways of improving the contract so that it can represent good value for money. Perhaps the starting point would be to conduct a study that assesses whether the extra benefits are worth the costs. It would be interesting to widen the scope of treatment costs to patients and families to include the cost of funerals and charities, and of transportation of deceased persons, and the indirect costs of periods away from normal work during bereavement for those in the same household and immediate neighbourhood.

It is advisable to conduct further study with a view to finding out the reasons for the higher spending at base health facilities located in bigger rural villages and towns. In addition, steps should be taken to control the situation through sensitisation if the high turnout at such facilities is found to be based on perceived quality difference between health facilities. Cost-centre specific costing may be conducted and costs collected for each health facility. In the same vein, the corresponding effectiveness rates may also be collected for each health facility.

With these, the cost-effectiveness ratios can be estimated per health facility and their combined ICERs estimated for the entire intervention. This should give the individual weights of the health facilities on the cost-effectiveness of the IPTp intervention and indicate variation in quality.

Finally, future research should expand the scope of this study to include all types of LBW, anaemia and malaria cases and can incorporate mortality and morbidity surveillance with a view to timely reporting any illness and deaths throughout the trial.

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APPENDICES

APPENDIX 1: INFORMATION EXTRACTION TOOL FOR EMPIRICAL THE LITERATURE REVIEW

SUMMARY OF EMPIRICAL FINDINGS ON MEASURING INDIRECT COSTS – SHEET 1

Author (s) and year of publication	STUDY BACKGROUND					
	Geographical setting of the study	Study population	Intervention evaluated	Types of costs identified	Type of forgone time included (paid/unpaid leisure)	Methods used to measure indirect costs

SUMMARY OF EMPIRICAL FINDINGS ON MEASURING INDIRECT COSTS – SHEET 2

COST MEASUREMENT AND VALUATION			
Approaches used to estimate indirect costs (HCA, FCA & WPA)	Consistent use of indirect costs	Indirect costs disaggregated from other costs	The effects of indirect costs on results assessed through sensitivity analysis

Definitions:
Paid work: Paid formal employment
Unpaid work: Any unpaid informal work such as preparing meals, childcare, other household work, subsistence, petty trading and other non-formal work
Leisure: Use of time except for paid and unpaid work i.e. sports, hobbies, socialising etc

APPENDIX 2: CLINIC QUESTIONNAIRE

MALARIA IN PREGNANCY STUDY: ECONOMICS COMPONENT

CLINIC QUESTIONNAIRE: SULFADOXINE/PYRIMETHAMINE (SP) IN MULTIGRAVIDAE

Date of Interview — **Day**|__|__| **Month**|__|__| **Year**|__|__|__|__|

Initials of fieldworker |__|__|__|

Identification number |__|__|__|__|__|__|__|__|

FH |__|__|

MALARIA IN PREGNANCY- CLINIC QUESTIONNAIRE

This questionnaire covers a range of areas such as the time spent in travel, waiting to receive care and the opportunity cost of the time of the pregnant mother accessing care at the clinic level. It also assesses the cost incurred in accessing care such as travel, treatment and food. It should be administered during the first visit of a pregnant mother attending Antenatal care.

SECTION 1: PATIENT TRAVEL COSTS

(1). **When did you leave your home for the clinic?**
Please probe to get the approximate time of departure and tick the appropriate answer below. Please specify if 10.

1. 6 am (*during the early morning prayers*) [ ]
2. 6.30 (*immediately after the early morning prayers*) [ ]
3. 7 am (*shortly before sunrise*) [ ]
4. 7.30 (*at sunrise*) [ ]
5. 8 am (*after sunrise/school going time*) [ ]
6. 8.30 (*well after sunrise*) [ ]
7. 9 am (after breakfast) [ ]
8. 9.30 -10 am (*Yorriyorri/Wolihha*) [ ]
10. Other (*Specify*)________________ [ ]
11. Don't know [ ]

(2). **How did you travel to this clinic?**
Please tick the appropriate answer and specify if 8

1. On foot [ ]
2. Bicycle [ ]
3. Motorbike [ ]
4. Public transport [ ]
5. Donkey/Horse/Ox cart [ ]
6. Taxi [ ]
7. Private transport (*including Government and NGO vehicles*) [ ]
8. Other (*specify*)________________ [ ]

(3). **If you travelled by paid transport, how much did you pay as fare?**
Please write the amount in dalasis and bututs in the spaces below.

Dalasis|__|__| **Bututs** |__|__|

(4) **When did you arrive at the clinic?** *Please tick the appropriate answer and specify if 10*

1. 6 am (*during the early morning prayers*) [ ]
2. 6.30 (*immediately after the early morning prayers*) [ ]
3. 7 am (*shortly before sunrise*) [ ]
4. 7.30 (*at sunrise*) [ ]
5. 8 am (*after sunrise/school going time*) [ ]
6. 8.30 (*well after sunrise*) [ ]
7. 9 am (after breakfast*)* [ ]
8. 9.30 –10 am (*Yorriyorri/Wolihha*) [ ]
10. Other (*Specify*)_______________________ [ ]
11. Don't know [ ]

(5) **How long did you wait before receiving <u>health care</u> at this clinic?**
Please tick the appropriate answer or write the time in hours and/or minute if possible

1.Did not wait [ ]
2.Just the time it takes to cook rice once [ ]
3. The time it takes to cook rice twice [ ]
4.The time it takes to cook rice three times [ ]
5.The time it takes to cook rice four times [ ]
6. Don't know [ ]

<u>TIME IN HOURS AND OR MINUTES</u>

Hours |___|___| **Minutes**|______|

(6) **How do you rate the time you waited before receiving health care at this clinic?**
Please tick the appropriate answer

1. Very short [ ]
2. Short [ ]
3. Neither short nor long [ ]
4. Long [ ]
5. Very long [ ]

(7). **Are you satisfied with the time you spent before receiving health care at this clinic?**
Please tick the appropriate answer

1. Very satisfied [ ]
2. Satisfied [ ]
3. Neither satisfied nor dissatisfied [ ]
4. Dissatisfied [ ]
5. Very dissatisfied [ ]

(8). **Did you <u>buy anything during your visit</u> to the clinic (for example, food, milk etc)?** *Please indicate what you bought and write the amount in dalasis and bututs in the space(s) below. Please tick 6 if you did not buy anything.*

1..**Dalasis**|___|___| **Bututs**|___|___|
2..**Dalasis**|___|___| **Bututs**|___|___|
3..**Dalasis**|___|___| **Bututs**|___|___|
4..**Dalasis**|___|___| **Bututs**|___|___|
5..**Dalasis**|___|___| **Bututs**|___|___|
6. Nothing
[ ]

(9). **How much do you want to spend on food, milk etc <u>on your way home</u>?** *Please indicate what you want to buy in dalasis and bututs in the space(s) below. Please tick 6 if you are not going to buy anything.*

1..**Dalasis**|___|___| **Bututs**|___|___|
2..**Dalasis**|___|___| **Bututs**|___|___|
3..**Dalasis**|___|___| **Bututs**|___|___|
4..**Dalasis**|___|___| **Bututs**|___|___|
5..**Dalasis**|___|___| **Bututs**|___|___|
6. Nothing [ ]

SECTION 2: OPPORTUNITY COST OF TIME

(10) What would you otherwise be doing had you not attend today's clinic?
Please tick the appropriate answer(s)

1. Household work.............................. [ ]
2. Trading... [ ]
3. Attending school (vocational)............... [ ]
4. Farming... [ ]
5. Paid work...................................... [ ]
6. Nothing... [ ]
7. Other (Specify)................................ [ ]

(11) If trading (2) or paid work (5), how much do you make on average per day?
Dalasis |__|__| **Bututs** |__|__|

(12) Who is doing your work while you are at the clinic?
Please tick the appropriate answer(s)
If nobody, please skip question 13 and go to question 14

1. Co-wife....................................... [ ]
2. Daughter..................................... [ ]
3. Aunt.. [ ]
4. Mother....................................... [ ]
5. Mother-in-law.............................. [ ]
6. Others (Specify)__________________ [ ]
7. Nobody...................................... [ ]

(13) **What is the normal work of the person doing your work while you are at the clinic?**
Please tick *more than one answer if applicable.*

1. Household work................................ [ ]
2. Trading.. .. [ ]
3. Attending school (vocational)................ [ ]
4. Farming.. [ ]
5. Paid work.................................. .... [ ]
6. Nothing.. [ ]
7. Other (Specify)................................. [ ]

(14) **How many days per week do you work when you are not sick at all?**
Please write the number of days in the space below.
Days: |__|

(15). **How many hours per day do you work on average when you are not sick at all?**
Please indicate the number of hours in the space below.
Number of hours |__|__|

(16) **Where applicable, how would you divide your daily time amongst the various activities below?**
Please probe to know whether she is not doing different work at the same time

Activity	**Estimated Duration**
Household work:	***(in hours and/or minutes)*** ***(You may otherwise estimate according to how long it takes to cook rice)***
Cleaning/sweeping	
Fetching water	
Pounding	
Cooking	
Washing	
Childcare	
Going to the Market	
Ironing	
Attending school / university	
Trading	
Farming	
Paid work	
Leisure	
Others (Specify)	

SECTION 3: FAMILY/VOLUNTEER CAREGIVER COSTS

(17) **Were you accompanied by a family member during your visit to the clinic today?** *(This should not include other women who have also come for clinic visit)*
1. Yes *(please continue on to question 18)*.................. [ ]
2. No *(please skip to question 20)*.................. [ ]

(18). **What is the work of the person(s) who accompanied you to the clinic?**
Please tick more than one answer if applicable.
1. Household work.............................. [ ]
2. Trading...................................... [ ]
3. Attending school (vocational).............. [ ]
4. Farming .... [ ]
5. Paid work.................................. [ ]
6. Nothing................................ [ ]
7. Other (Specify)............................. [ ]

(19) **What is the reason for being accompanied by a family member to the clinic?**

....

(20) **Will you go home straight after the clinic visit?**

Please tick the appropriate answer

1. Yes [ ]
2. No [ ]

Interviewer....................................	**Checked by**:..........................

APPENDIX 3: FOLLOW-UP QUESTIONNAIRE

MALARIA IN PREGNANCY STUDY: ECONOMICS COMPONENT

FOLLOW-UP 1 QUESTIONNAIRE: SULFADOXINE/PYRIMETHAMINE (SP) IN MULTIGRAVIDAE

Identification Number
|__|__|__|__|__|__|__|

Follow-up date

Day|__|__|

Month|__|__|

Year|__|__|__|__|

Initials of Fieldworker
|__|__|__|

MALARIA IN PREGNANCY- FOLLOW-UP QUESTIONNAIRE

This questionnaire solicits information related to the background characteristics of the household head and the household assets. It further assesses whether the recruited mother got sick during her term of pregnancy until she gave birth to her baby. If she got sick, follow-up questions are asked to establish what sort of steps she took, the type of care she received, costs incurred and the opportunity cost of her time. If sick and she did not seek care, reasons for not seeking care should be advanced.

SECTION 1: SOCIO-DEMOGRAPHICS

(1) What gender is your household head?
Please tick the appropriate answer. If male, go to 2, otherwise skip to 3
1. Male [ ]
2 . Female [ ]

(2). **How many wives does the household head currently have?**
Please tick the appropriate answer.
1. None............................ [ ]
2. One............................ [ ]
3. Two............................ [ ]
4. Three............................ [ ]
5. Four............................ [ ]

(3 **What level of education has your household head completed?**
Please tick the appropriate answer(s)
1. None [ ]
2. Primary [ ]
3. Secondary [ ]
4. Tertiary [ ]
5. Madrassa [ ]
6. Non-Formal [ ]

(4) **If Madrassa or Non-Formal education, how many years were spent in learning**
1. Number of years |__|__|**2. Do not know** |__|

(5). **What is the main occupation of the household head?**

1. Farmer.................................. [ ]
2. Herdsman.............................. [ ]
3. Shopkeeper/Retail.................... .. [ ]
4. Business............................... [ ]
5. Nurse.................................... [ ]
6. Domestic work......................... [ ]
7. Other (Please specify)................. [ ]

(6). **Does anyone in the household own the following? If so, how many of each?**

Please write the number of assets in the boxes provided. For example, if there were two watches you would write: (2). If none then write zero in the box provided.

1. Radio...................... .... |__|
2. Radio cassette player................. |__|
3. Iron bed or carved wood bed......... |__|
4. Bicycle................................ |__|
5. Horse cart............................. |__|
6. Donkey cart........................... |__|
7. Ox cart................................ |__|
8. Corrugated roof...................... |__|
9. TV...................................... |__|
10. Motorbike or car.................. |__|
11. Clock/Watch........................ |__|
12. Telephone/Mobile .... |__|

(7). **Does anyone in your household own livestock?**
If so, how many of each?

Please write the appropriate number of assets in the boxes provided. For example, if there were hundred cattle, please write (100) in the boxes provided. If none then write zero in the box provided.

1. Chicken................................ |__|__|__|
2. Cattle.................................. |__|__|__|
3. Sheep.................................. |__|__|__|
4. Goats.................................. |__|__|__|
5. Horses................................. |__|__|__|
6. Donkeys............................... |__|__|__|

(8). **What source of fuel do you use for cooking?**

Please tick the appropriate answer

1. Collected firewood.................... .. [ ]
2. Purchased firewood.................. .. [ ]
3. Gas..................................... .. [ ]
4. Electricity............................. ... [ ]
5. Crop residues......................... ... [ ]
6. Charcoal.............................. .... [ ]
7. Kerosene................................ [ ]
8. Other (Specify)......................... [ ]

SECTION 2: HEALTH AND SOCIAL CARE PROFESSIONAL COSTS

(9). **During the past four weeks have you been sick?**

Please tick the appropriate answer

1. Yes (please continue with question 10)............. [ ]
2. No (go to the end and sign the questionnaire).... [ ]

(10) **How many days in the past four weeks have you been sick?**

Please write the number of days of sickness in the space below.

Days of sickness |__|__|

(11). ***How severe was the sickness?***
Please tick the appropriate answer
1. Mild (able to do normal work)........................ [ ]
2. Moderate (able to do normal work with difficulty) [ ]
3. Severe (unable to do normal work) .... [ ]

(12). Did you get better? Please tick the appropriate answer
1. Yes .... [ ]
2. No still moderately sick............................ [ ]
3. No still seriously sick .... [ ]

(13). **For how many days <u>during your sickness were</u> you unable to carry on your usual activities/work?**

Please write the number of days. If none, write 0
Days with no usual activities |__|__|

If applicable, how many <u>hours per day on average</u> did you work on days of your sickness when you were able to do work normally? *Please write the number of reduced hours. If none, write zero*
Reduced hours of work during sickness |__|__|

(15). **Did you seek care while you were sick?**
Please tick the appropriate answer
1. Yes (please continue with question 16)...... .... [ ]
2. No (go to question 21) .... [ ]

(16). Where did you seek care?
Please write the number of visits, the estimated duration and cost of visits in the spaces provided. Put zero if no visit took place in the last four weeks.

Health provider	**Please tick Yes or No**		**No. of visits**	**Estimated duration of visit**		**Cost of Treatment**	**Cost of food**	**Cost of Transport**
				Days	**Hours**			
Hospital/Health Centre	**Yes**	**No**						
Outpatient only								
Admitted/ Inpatient								
Clinic/Dispensary	**Yes**	**No**						
Outpatient only								
Admitted/ Inpatient								
	Yes	**No**						
CHN								
VHW								
Pharmacy (where they sell drugs and related items)				–				
Shop/Kiosk *(where they sell mainly other goods and some few drugs)*				–				
Traditional Healer								
Other (Specify)								

(17). **How long did you wait before receiving treatment at the health facility?**
Please tick the appropriate answer
Please write the time in hours and/or minute if possible. If you did not wait please write zero
1. Did not wait [ ]
2. The time it takes to cook rice once [ ]
3. The time it takes to cook rice two times [ ]
4. The time it takes to cook rice three times [ ]
5. The time it takes to cook rice four times [ ]
6. Don't know [ ]

<u>PLEASE ASK HER TO INDICATE THE TIME IN HOURS AND/OR MINUTES IF SHE CAN</u>.

Hours |___|___| **Minutes**[ ]

Please ask only those who were admitted (Questions 18-20)

(18). **While admitted, how many people on average on each day visited you?**
Please write the appropriate number of visitors in the space below: If you are not admitted, please skip to question 22
Number of visitors per day |___|___|

(19). **How long did your visitors stay?**

Please write the average number of hours and/or minutes in the space below
Average time stayed by visitor: Hours: |___|___| Minutes |___|___|

(20). How far on average do your visitors live from your place of admission?
Please write the appropriate distance in kilometres in the space below.
Number of kilometres |___|___|___|

Please ask only those who did not seek care (Questions 21-22)

(21). **Why didn't you seek treatment/care?**
Please tick the appropriate answer
1. Illness not severe .... [ ]
2. Did not trust treatment..................... [ ]
3. Lack of money (includes lack of fare) .... [ ]
4. Facility too far away.................... .... [ ]
5. Could not get transport........................ . [ ]
6. Facility not open.............................. [ ]
7. Family would not let me..................... [ ]
8. Busy at work................................ . [ ]
9. Busy at home................................. [ ]
10. No permission from husband.............. [ ]
11. Nobody to do the work..................... [ ]
12. Already have some drugs in the house...... [ ]
13. Other (Please specify)........................... [ ]

(22). **Please place in order the barriers to accessing care, starting with the most serious one, second most serious etc**
Please rank in ascending order starting with the with 1 as the most contributing factor for not accessing care, 2, the second most and 3 etc
1. Illness severe enough.................... |___|___|
2. Did not trust treatment.................... |___|___|
3. Lack of enough money (includes lack of fare) |___|___|
4. Facility too far away............................ |___|___|
5. Could not get transport........................... |___|___|
6. Facility not open................................. |___|___|
7. Family would not let me......................... |___|___|
8. Busy at work...................................... |___|___|
9. Busy at home.................................... |___|___|
10. No permission from husband................. |___|___|
11. Nobody to do the work..................... |___|___|
12. Already have some drugs in the house...... |___|___|
13. Other (Please specify).......................... |___|___|

SECTION 3: INFORMAL CARE/HOME HELP COSTS

(23) In the last four weeks, have you been helped and/or cared for by a relative, friend or paid assistant either at home or at the hospital because of your sickness? *Please tick the appropriate answer.*

1. Yes (please continue with question 25) [ ]
2. No (go to question 26) [ ]

(24). **In the past four weeks, how many relatives or friends or paid assistants etc helped and/or cared for you because of your sickness?** *Please complete the table below by indicating the age, main occupation, the place the helper comes from, number of helpers and number of hours helped.*

Category of helper	**Age**	**Occupation of helper**	**Place the helper comes from**	**No. of helpers**	**No of days helped**	**No. of hours per day helped**
Relatives						
Friends						
Paid assistants						
Other (specify)						

(25). **Do you have any further comments or any information you would like to add about the cost to you of accessing care while sick?**

....

......

Interviewer.. **Checked by**:............................

APPENDIX 4: MANUAL OF PROCEDURE

GENERAL INTRODUCTION OF FIELDWORKERS TO EXPECTANT MOTHERS

I am (Name)..from
the Medical Research Council (MRC) conducting a study on malaria in pregnancy. Through this study, we solicit information from selected expectant mothers to find out what costs they incur in accessing care during their pregnancy until they gave birth. This study is very crucial in ensuring that access to care is assured if we are to reduce both infant and maternal mortality in the Gambia. Therefore, your participation and co-operation will be highly appreciated.

The information that you will provide will be used solely for improving the quality of care of mothers and children in the Gambia and will always be kept confidential.

MALARIA IN PREGNANCY STUDY: ECONOMICS COMPONENT SULFADOXINE/PYRIMETHAMINE (SP) IN MULTIGRAVIDAE STUDY

Purpose of the study
The economic component of the Malaria in Pregnancy Trial will assess the cost, effectiveness and cost-effectiveness of using sulfadoxine-pyrimethamine (SP) through Intermittent Preventive Treatment (IPT) for multigravidae (i.e. pregnant women with more than one birth). This is in response to the need to gather enough evidence that will inform policy especially in light of problems encountered because of non-use of prophylaxis for pregnant women in The Gambia. Specific costs such as those related to accessing care by patients and their families at the clinic level, waiting time cost, household costs in terms of the opportunity cost of time, clinics and hospitals admission costs to the patients for treating and caring for pre-term babies and anaemic mothers will be included. Like in the effectiveness component, pregnant women enrolled in the economic analysis will be monitored for up to six weeks after delivery.

This study proposes to look more deeply into the issue of what constitutes indirect costs in a rural Gambian population, and will make use of the sample of a randomised Controlled trial of intermittent SP for prophylaxis in pregnant women in The Gambia. It has been argued that, in order for intermittent treatment to be effective and beneficial to people, pregnant women need to take it between three and four times before delivery. Since the trial is clinic-based, pregnant women need to attend clinic for the same number of times before giving birth.

Therefore, those who are worse off are those who never attend antenatal clinics and those who are not able to complete the treatment during their pregnancy. The intervention is to be assessed in terms of overall cost-effectiveness, but measuring this alone may hide possible negative effects on inequalities, with those women whose indirect costs are high, benefiting least from the intervention, and vice versa. For the purpose of this aspect of the study, the following sets of instruments will be used:

1. **Clinic exit questionnaire**
2. **Four weekly Follow-up questionnaire**

Some of the contents of the instruments were adapted from previous tools used in both developed and developing countries. They have been adapted to suit the content and logistic requirements of the trial.

The study will help estimate both the financial and non-financial resources pregnant women and their families incur when accessing antenatal care in **14** clinics; eight in the North Bank and six in Lower River Divisions of the Gambia. Through the administration of two questionnaires, clinic exit and follow-up, the study will obtain firsthand information from the pregnant women on the cost they incur in accessing care at the clinic level. Since the study results will be aggregated, the individual information will only be an input into the overall framework and therefore confidentiality is automatically guaranteed. Each answer obtained will be combined with those of other patients involved in the study and will be reported in such a way that no individual will be identifiable through the report. The economic aspect of the trial is a sub-component of the main trial and so all the conditions that apply in the main Malaria in Pregnancy (MIP) trial also apply here.

GUIDE TO FIELDWORKERS

The questionnaires have as far as possible been numbered chronologically. Since the clinic and follow-up questionnaires are to be administered separately from other instruments in the trial, identification numbers have been included for easy identification and assembling with other instruments especially the effectiveness questionnaire. The relevance of each of the questions to the study has been assessed and it was found out that all of them are equally relevant and so all attempts should be made to complete them fully. The appropriate recall period is four (4) weeks in most cases for the simple reason that the duration between two visits to antenatal clinic is four (4) **weeks** in the early stages of pregnancy in the Gambia.

CLINIC EXIT QUESTIONNAIRE

This questionnaire covers a range of areas such as the time spent in travel, waiting to receive care and the opportunity cost of the time of the pregnant woman while accessing care at the clinic level. It also assesses the cost incurred in accessing care such as travel, treatment and food. It should be administered during the first visit of a pregnant woman attending Antenatal care. This questionnaire will be administered to all expectant mothers within our sample. The questions included in this document are suitable for completion by expectant mothers themselves but the high illiteracy level in the Gambia would make that difficult if not impossible. Therefore, under the circumstances, the study will rely on the services of fieldworkers to effectively and accurately administer the questionnaire. Specific instructions for the fieldworkers are in *italics* after each question. Italics are also used to offer guidance throughout the questionnaire. Where it is believed that the question is not exhaustive, additional spaces have been added to capture all the possible answers.

CLINIC QUESTIONNAIRE
SECTION 1: patient travel cost

Section 1 covers questions 1-9 that assess travelling time, mode of transport, and cost incurred.

Q1: Given the problem in knowing time because of the high illiteracy level, the answers are related to things such as early morning prayers, sunrise etc. Where it is found to be possible to state the time, there may not be any need to ask these questions. A little bit of questioning is necessary in order to establish the estimated time.

Q2: The pilot has revealed that most people walk to the clinic, which means Q3 should be skipped. For other modes of transport such as bicycle, motorbike, private transport etc, it might not be possible to indicate the fare paid. However, it might be possible to further probe to find out whether any fare has been paid regardless of the option chosen except on foot.

Q3: This only gives the opportunity to indicate the fare paid if respondents use paid transport.

Q4: When the arrival time is not known, conventional time should be linked to the common activities people know such as morning prayers, sunrise, school-going time etc. Like any question that requires time, a little bit of probing is necessary here.

*Q5: Because of the difficulty it takes to understand time, one common aspect every woman knows in the Gambia is the time it takes to cook rice (just rice). For instances if it takes 1 hour to cook rice once, then cooking rice twice will be 2 hours (1*2). If at all the time can be estimated without difficulty, it is better to use that option.*

Q6: This question tries to find out expectant mothers' perception regarding how long they waited before receiving care.

Q7: This question tries to establish the level of satisfaction or dissatisfaction of the pregnant mothers concerning the time they spend before receiving care.

Q8: Women often buy something at the clinic either through the advice of health practitioner or on their own volition. Whatever the reason, this should be captured. It is very common for them to buy something before being seen by the health provider. Any such costs should be recorded here.

Q9: It has been proven through the trial that some expectant mothers do buy things after receiving care on their way home. It is therefore necessary that we ask them what they intend to buy and how much they will spend on their way home. Any such costs should be recorded here.

SECTION 2: OPPORTUNITY COST OF TIME

This section covers questions 10-16 and asks how the attendance of the expectant mother at the clinic affected both her work (paid and unpaid). Unpaid work includes all aspects of household chores such as meal preparation, cleaning, taking care of children, leisure etc. These questions are asked after the woman has accessed the service in order for her to assess whether there is enough time left for her to do other work.

Q10: Attending clinic has time cost in terms of alternative activity the person would otherwise been doing. The appropriate box should be ticked and if 7, specify. It is very common for people to have more than one profession and so only things that cannot be done at the same time are supposed to be recorded.

Q11: For those who are trading or doing paid work, you should reflect how much they make on average per day.

Q12.: This question gives the opportunity to indicate who was doing the work while the expectant mother was at the clinic. For most people, it is the daughter, aunt or co-wife etc. Whatever the answer, indicates accordingly.

Q13: The normal work of the person doing the work while the expectant mother is at the clinic should be indicated here. As was the case in **Q10,** some people normally have more than one job and if this is the case, then it should be mentioned. However, for different activities done at the same time, only one should be recorded.

Q14: This means the number of days worked per week. For most ladies, rest days fall on Wednesdays and Fridays but even these two so-called rest days are used to do some other group work or domestic work. You should probe to find out what activities are carried out and record the appropriate answer.

Q15: Please indicate here the number of hours of work the expectant mother does per day. Most people might not be able to say this but a little bit of probing could be helpful in getting the answer. For example, when do you go to the fields and when do you come back?

Q16: This is just to help give the correct estimate for Q15. By answering this question, the study should be able to get a closer estimate of what has been given in Q15. Please do not spend time to balance the two. Just ask the questions and write the answers, of course with a little bit of probing.

SECTION 3: FAMILY /VOLUNTEERS CAREGIVER COST

Section 3 covers questions 17-20 and is not entirely different from the previous two sections except that they are not for the patient but for anybody who accompanies her to the clinic. It also includes the travel, feeding and opportunity cost of the time for that person.

Q17: This probes whether the expectant mother came to the clinic alone or with someone. This does not include women who came to the clinic with her to seek health care themselves. She needs to say 'Yes' or 'No'. If the answer is 'NO', then skip to question 20. On the other hand if it is 'YES', then you should proceed to Q19 for her to tell you the work of the person who accompanied her.

Q18: Like in question 13, the normal work of the person accompanying the expectant mother to the clinic should be indicated here. As is the case, some people normally have more than one job and if this is the case here, then it should be mentioned. However, for different activities done at the same time, only one should be recorded.

Q19: Question 19 seeks to find out the reason the expectant mother is being accompanied to the clinic. This is an open-ended question.

Q20: Question 20 seeks to find out whether the expectant mother went home straight after the clinic.

Please **Remember**! Always sign the form.

FOLLOW-UP QUESTIONNAIRE

The follow-up questionnaire requires multiple visits, **four weeks** have been considered appropriate for the recall period. This questionnaire solicits information related to the background characteristics of the household head and the household assets. It further assesses whether the recruited expectant mother got sick during her term of pregnancy until she gave birth to her baby. If she got sick, follow-up questions are asked to establish what sort of steps she took, the type of care she received, costs incurred and the opportunity cost of her time. If she got sick and she did not seek care, reasons for not seeking care should be given.

FOLLOW-UP QUESTIONNAIRE

SECTION 1: SOCIO-DEMOGRAPHICS

This section covers questions **1-8** which mainly asks about household head background characteristics and household assets.

Q1: This asks the gender of the household head. Your work is to tick the appropriate answer.

Q2: Question 2 only seeks information on the number of wives the household head has and you should just tick the correct answer.

Q3: This one probes the level of education of the household head. Please tick the appropriate answer(s). Please indicate the levels that have been fully completed.

Q4: Question 4 asks if household head has non-formal education or Madrassa and then finds out the number of years of schooling s/he has attended. Since this questionnaire is administered at the home of the expectant mother, you may seize the opportunity to ask the household head.

Q5: Some people in the Gambia especially men, have more than one occupation. In cases where that is the case, only the main occupation should be selected. For example, you may ask the main source of income, which may give an indication as to the real occupation of the household head.

Q6: This question seeks to establish the type of assets the household has. Some of these answers are easily verifiable and so you should be vigilant. For example, you may find someone in the household listening to a radio.

*Q7: Some people normally do not want to count their living animals for various reasons and as such soliciting answers to this question has not been easy in the pilot. It is therefore advisable to do a lot of probing here. Some would say for example their chickens are more than 10 without being specific. In such instances, it is your role to ask **whether they are up** to 20. If she answers in the negative, you may come down to 15 until you are sure that you have a reasonable answer.*

Q8: This is the question on source of fuel used for cooking by the household. The answer here is centred on four items but that is not to say that other forms are not used. Please ask and accordingly tick the appropriate answer without pre-empting.

SECTION 2: HEALTH AND SOCIAL CARE PROFESSIONAL COSTS

This section covers questions **Q9-22** and is mainly about any sickness during the four-week interval and whether any medical attention has been sought regardless of location. Please remember that cost could be incurred without actually going to the modern health facility, as there are many other ways to treat illness. There is provision for all those possibilities.

Q9: This seeks to find out whether the person has been sick or not. If the answer is in the positive then you should go to the next question otherwise go to the end of the questionnaire and sign.

Q10: This is just to get the number of days the person has been sick. i.e. start to end dates.

Q11: This is only to know the seriousness of the sickness. Since seriousness is relative from person to person, it has been decided to link it to the ability to carry out normal work.

Q12: This question tries to find out whether the person is better or not and if not what was the state of sickness.

Q13: People can be sick and still be able to carry on with their normal work but in some instances, they may not be able to work. This question seeks to find out from the respondent the number of days she was not able to carry on with her usual activities.

Q14: People can work on reduced hours when sick. Our interest is first to know the number of days the person has been sick **(Q10)**, then the number of days she was unable to do any work whatsoever. **(Q13)** and this question **(Q14)** try to find out the number of days she worked on reduced hours if applicable.

Q15: It is very common for people in this part of the world not to seek health care at all times when sick. They may want to get into some coping strategies in the interim. We want to know from this question whether the woman sought care or not. If the answer is in the positive, then go to the next question otherwise skip to **Q21.**

Q16: The table in this question gives the expectant mother the chance to catalogue which health provider she visited and these could range from formal to informal care. Please note that outpatient can only be for hours and any period spent at the facility above 23 hours qualifies as admission. It has been assumed that one cannot be admitted for hours. Therefore, do not fill the black squares where they exist, as they are not applicable to the health facility or the provider concerned.

Q17: This question asks the time the expectant mother waited before receiving care. It has been approximated to the time it takes to cook rice, which is a familiar activity to every woman in the Gambia. What it means here is the cooking of plain rice and not any accompanying sauce. However, if the expectant mother knows the time, it might not be necessary to use the rice-cooking example. In that case, just go straight to the conventional time

Q18: This question refers to only those expectant mothers who have been admitted. It asks for the number of people that visited the expectant mother while admitted. Unless in very rare case that the person has no relatives in the country, visiting people at hospitals is a common phenomenon in the Gambia. Our interest is the average number of people (visitors) per day.

Q19: We do not expect people to know the exact times their visitors come and go but they should be able to give the average time they normally stay. If they cannot not tell, the rice-cooking example can be given with the assumption that it takes about an hour to cook rice. You may also find out about the visiting hours in the health facilities concerned.

Q20: It might be difficult for all the patients to know where their visitors come from. However, being a fieldworker in the area, it will be possible to tell the places they come from and you can estimate travelling time. If need be, write the name of the place so that you can crosscheck later. Using the kilometre counter on your motorbike could be a very useful tool for this purpose.

Q21: There are several reasons why people do not seek care. The expectant mother is free to indicate more than one reason if applicable and so you should probe further and tick the appropriate answer(s).

Q22: This gives the opportunity to rank the reasons in terms of the "most" to the "least" barriers to accessing care while sick starting with number 1, then 2 then 3, 4 5 etc. Please write the appropriate numbers in the boxes provided.

SECTION 3: INFORMAL CARE/HOME HELP COSTS

This section covers questions **23-25** and asks about any support the expectant mother may have received at home because of her sickness. By home-helper, we mean any person who is either employed or comes on voluntary basis help to carry out tasks on behalf of the expectant mother while she is sick. The work includes cleaning the house, ironing or gardening etc. Here the interest is only in the assistance she needed and was given because of her sickness and not for any other reason.

Q23: This question asks whether the woman has been helped in any way because of the sickness she had. You should go to Q24 if the answer is positive otherwise you should skip to Q25.

Q24: This question gives the expectant mother the opportunity to indicate the type of helpers; whether relatives, friends, paid assistants or others. The age of the helper must be recorded in order to find out whether s/he is a minor. The usual occupation and the place the helper comes from should also be recorded. You should also ask her to indicate the number of helpers, number of days helped and the average number of days per hour.

Q25: Question 25 gives the expectant mother the opportunity to say anything about costs she could have incurred or the opportunity cost of time during her sickness not taken care of in any of the questions asked earlier.

Always **Remember**! To thank the woman for her time and co-operation and sign the questionnaire.

For any queries or questions, please contact:

Pa Lamin Beyai
MRC Filed Station
Farafenni, North Bank Division
Telephone:
OR
Telephone: 462283/4/6
Mobile: 901686
Email: Pa-Lamin.Beyai@lshtm.ac.uk

APPENDIX 5: SAMPLE SIZE CALCULATIONS

Sample size calculations for Malaria in pregnancy trial
The details of how the sample size was reached are indicated below. The primary endpoints of the trial are anaemia status (Hb <9g/dl) in the post partum period and low birth weight (LBW< 2500g) in multigravidae. To be able to observe with 80% power and 5% level of significance, a 20% reduction from the current estimated risk of anaemia (Hb < 9 g/dl) of 30% to 24% of multigravidae during both the rainy and the dry season, and allowing for 20% combined refusals and loss to follow-up, a sample size of 2 x 1,115 was estimated to be sufficient (90% power 2x1478). The same estimation to observe a 75g difference in mean birth weight (increase from 3,000g to 3,075g; SD 500g) during both the rainy and the dry season would need a sample size of 2 x 874 (90% power 2x1169), while the sample size needed to show a reduction in proportion in LBW (<2500 g) from 16% to 12% is estimated at 2x1538.

Sample size calculations for economic component of MIP
In order to obtain the required sub-sample of the economic study, the researcher made use of Pocock (1983) and received assistance from a statistician at the LSHTM. The size of the sample (n) was calculated using the efficacy rate for IPT with SP for pregnant women in Malawi and Kenya. The respective rates of LBW before and after taking two doses of SP as IPT at the antenatal clinic are 23% and 7% with IPT and the corresponding figures for Malawi are 23% and 10% respectively. The joint efficacy of the two leads to averages of 23% and 8.5% without and with IPT. To calculate the size of our sample, the following formula was used:

$$n = \frac{P_0 * (100 - P_0) + P1 * (100 - P_1).}{(P_1 - P_0)^2} f(\alpha, \beta)$$

Where P_0 is the percentage of LBW babies with placebo
P_1 = percentage of LBW babies with two doses of SP
α = the level of the significance test used for detecting treatment difference (α = 0.050 = 5%)
$1-\beta$ is the degree of certainty that P_0-P_1, if present would be detected ($1-\beta$ = 0.90) @ 90% which is the power to detect a difference of magnitude P_0-P_1
α = Type I error, represents the risk of a false-positive result
β = Type II error, represents the risk of a false-negative result

The formula above produced a total sample size of 254 or 127 per arm. This was rounded up to 300 (150 each arm in order to account for any dropouts.

APPENDIX 6: EMPLOYMENT SURVEY FORM

Example of the work and pay of domestic maids						
ID	**Health District**	**Duration**	**Hours**	**Pay**	**in kind**	**Composition of work**
1	LRD	8am-5pm	9	200		cooking, sweeping, laundry, errands, washing and ironing
2	LRD	8am-1pm	5	600		
3	LRD					
4	LRD					
5	LRD	8am-1pm	5	1,000		laundry and ironing
6	LRD	8am-6pm	10	225		cooking, washing, sweeping, ironing
7	LRD	8am-5pm	9	350		sweeping, laundry, fetching water, ironing, childcare
8	LRD	9am-5pm	8	200		Cleaning: house, bowls, laundry, errands, cooking, ironing
9	LRD	8am-7pm	11	500		laundry ironing, house fitting, cooking, sweeping
10	LRD	8am-6pm	10	1,000		laundry, cooking, sweeping, ironing
11	LRD	8am-6pm	10	600		laundry, ironing, sweeping, cleaning
12	LRD					
13	LRD	8am-1pm	5	800		laundry, ironing, cleaning
14	LRD	8-1pm	5	900		laundry, ironing, cleaning
15	LRD	7-6pm	11	1,500		sweeping, cooking, washing, ironing
16	LRD	8-6pm	11	300		childcare, cooking, washing, ironing, cleaning
17	LRD	8-2pm	6	300		sweeping, ironing, laundry, errands, washing
18	LRD	8-2pm	6	250		sweeping, washing, laundry, ironing
19	LRD	8-7pm	11	250		laundry, ironing, cleaning, sweeping, baby caring
20	LRD	7-6pm	11	200		cooking, laundry, sweeping
Average						

APPENDIX 7: FORM 1: PATIENT COST DATA COLLECTION

OUTPATIENTS DEPARTMENT FORM FOR ALL PATIENTS

Day of the week................................	**Date of the week:** / /
Name of fieldworker:...	**Initials of fieldworker**|___|___|

1. Arrival Time |___|___|___|___|

2. Cashier:
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

3. Medical Records:
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

OUTPATIENTS DEPARTMENT FORM FOR: ANAEMIA / LOW BIRTH WEIGHT

Day of the week................................	**Date of the week:** / /
Name of fieldworker:...	**Initials of fieldworker**|___|___|

1. General Consulting/Obstetrics
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

2. Name of Patient.......................................

3. Age: |___|___| **4. Number of children** |___|___| **5. Work**...................................

5. Sex (LBW babies only) Male/Female **6. Accompanied:** Yes/No **7a. Age of Escort:** Adult/Child

7b. Number of escorts:......

8. Diagnosis: LBW/Anaemia **8a. If Anaemia, Haemoglobin (HB) level**......dl **8b. If LBW weight** ....kg

9. Pharmacy:
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

10. Laboratory (if applicable):
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

11. X-ray (if applicable):
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

12. Back to General Consulting/Obstetrics (if applicable)
Time reached |___|___|___|___| Time seen |___|___|___|___| Time left |___|___|___|___|

13. End of treatment and out of the hospital |___|___|___|___|

14. Time of Admission |___|___|___|___|

PLEASE ASK THIS FORM FOR THOSE ADMITTED ONLY

Day of the week................................ **Date of the week:** / /

Name of fieldworker:... **Initials of fieldworker**|___|___|

1. Name of patient admitted...
2. Parity.................
3. Haemoglobin level ....dl
4. While admitted, how many people visited the patient?
Number of visitors |___|___|

5. Length of stay of visitors?
Arrival time of visitor: |___|___|___|___| **Departure time of visitors** |___|___|___|___|

6. Where did the visitors come from?
Origin of visitors:.......................................

7a. How many are adults |___|___| **7b. How many are children** |___|___|

8a. How did the visitors travel to this clinic? ....

8b. If paid Transport (fares paid) |___|___|___|___|

9. Gifts brought *(Please number, size and amount if money)*
1...
2...
3...
4...
5...
6...
10. Departure time of visitors |___|___|___|___|

Important Note: *Each form should be filled for a group of visitors NOT per visitor*

MISSING

PRINT

/N ANALYSIS OF AFPRCH COSTS (D)

Staff number	Area in metre square	Beds	Admissions/ contacts	ALoS	Patient Day	Annuitised equipment cost	Annual gross pay 2003	Cost	Training	Drugs	Stationery
						1,857,462			2%	(Maternity D9.94)	
									0.02	(Paed D6.57)	
										(OPD D46.75)	
21	539	21	564	7	3,948	81,638	256,634		5,133	39,243	
8	97	15	3,079	7	21,553	118,010	154,277		3,086		
14	539	26	1,040	4	4,160	70,689	175,302		3,506		
8	539	16	274	30	8,220	45,650	88,129		1,763		
21	539	30	2,228	15	33,420	65,454	282,176		5,644	332,195	
4	539	12	35	60	2,100	22,687	44,817		896		
76	2,792	120	7,220	123	73,401	404,128	1,001,335	0	20,028	371,438	0
18	121	0	0	0	0	471,748	216,807	0	4,336	0	46,529
5	45					359,685	92,971		1,859		8,294
17	604		299			280,230	264,433		5,289		
7	25					15,414	108,932		2,179		87,087
2	99					69,281	21,885		438		
3	16					7,894	26,102		522		
59	161		10,645			77,614	694,822		13,896	497,654	
111	1,071	0	10,944	0	0	1,281,866	1,425,952	0	28,519	497,654	141,910
66	651					121,024	897,955		17,959		34,862
								1,040,400	0		
27	539					27,975	251,737	136,440	5,035		
32							305,706		6,114		
9						36,456	114,273		2,285		
5							31,555		631		
139	1,190	0	0	0	0	185,455	1,601,226	1,176,840	32,024	0	34,862
0	0	0	0	0	0	0	0	0	0	0	0
326	5,053	120	18,164	123	73,401	1,871,449	4,028,513	1,176,840	80,571	869,092	176,772

m	Telecom	Utilities (elec & water	Vehicle	Building maintenance	Administration	Fuel	Domestic	Security & Gardening	Maintenance
	120,000	324,000	82,812	3,653,009	1,659,174	1,040,400	1,159,015	663,854	255,180
					260		996,753	3,860	3,860
	7,730	34,561	8,833	389,664	134,010	84,032	192,425	92,699	35,633
	2,945	6,220	1,590	70,125	51,052	32,012	34,629	16,682	6,413
	5,153	34,561	8,833	389,664	89,340	56,022	192,425	92,699	35,633
	2,945	34,561	8,833	389,664	51,052	32,012	192,425	92,699	35,633
	7,730	34,561	8,833	389,664	134,010	84,032	192,425	92,699	35,633
	1,472	34,561	8,833	389,664	25,526	16,006	192,425	92,699	35,633
)	27,975	179,025	45,755	2,018,445	484,990	304,116	996,754	480,177	184,578
							162,262		
	6,626	7,759	1,983	87,476	114,866	72,028	18,349	20,810	7,999
	1,840	2,885	737	32,532	31,907	20,008	6,824	7,739	2,975
	6,258	38,729	9,899	436,655	108,484	68,026	91,595	103,878	39,930
	2,577	1,603	410	18,073	44,670	28,011	3,791	4,300	1,653
	736	6,348	1,622	71,571	12,763	8,003	15,013	17,026	6,545
	1,104	1,026	262	11,567	19,144	12,005	2,426	2,752	1,058
)	21,718	10,323	2,639	116,393	376,505	236,091	24,415	27,689	10,644
)	40,859	68,673	17,552	774,267	708,339	444,172	162,413	184,194	70,804
)	24,294	41,742	10,669	470,633					
		0	0	0					
	9,939	34,561	8,833	389,664	172,299	108,042			
	11,779	0	0	0	204,206	128,049	0		
	3,313	0	0	0	57,433	36,014	0		
	1,840	0	0	0	31,907	20,008	0		
	0	0	0	0	0	0	0		
)	51,165	76,303	19,502	860,297	465,845	292,113	0	0	0
			0	0					
	0	0	0	0	0	0	0	0	0
)	119,999	324,001	82,809	3,653,009	1,659,174	1,040,401	1,159,015	664,371	255,382

Radiology	Main theatre	Pharmacy	Dental	Physiotherapy	Total cost	Unit cost/admission	Unit cost/patient day
580,262	1,485,448	324,171	241,707	94,713			
499,025	1,277,485						
26,841	68,712	15,228			1,663,345	2,949	421
146,531	375,113	83,131			2,015,411	655	94
28,282	72,401	16,045			1,468,003	1,412	353
55,885	143,062	31,705			1,571,815	5,737	191
227,210	581,648	128,903			4,026,099	1,807	120
14,277	36,549	8,100			1,032,913	29,512	492
499,026	1,277,485	283,112	0	0	1,962,931	7,012	279
81,237	207,963						
		0	0	0	1,095,445		
					580,262		
2,219					1,485,448		
0	0				324,171		
0	0	0			241,707		
0	0	0			94,713		
79,018	207,963	41,058	241,707	94,713	2,965,641	271	
81,237	207,963	41,058	241,707	94,713	6,787,387		
					1,659,174		
					1,040,400		
					1,159,015		
					663,854		
					255,180		
					87,191		
0	0	0	0	0	4,156,320		
					13,200		
0	0	0	0	0	13,200		
580,263	1,485,448	324,170	241,707	94,713	12,919,838		

APPENDIX 9: HOUSEHOLD TIME USE DIARY

Name of HH Head.............................	**Village:... ..... Health District:...**
Name of interviewee:......... Parity:.........	**Day of week:.. Date of interview:...........................**
Number of people in the HH:...................... Number of adults:......................... Number of C\children:.........	**Health Centre use for ANC:........................... Distance:...**
Main Activity	**Parallel Activity**

Start Time	**Stop Time**	**Name**	**Code**	**Time used**		**Yes = 1 No = 2**	**Name**	**Code**	**Time used**	

APPENDIX 10: TRIAL INTERNATIONAL CLASSIFICATION OF TIME USE ACTIVITIES

Trial International Classification of Time use Activities

1. Time use of multigravidae (15 to 49 years old) in household

2. Questionnaire and instruction for interviewers

The questionnaire describes a list of economic, domestic, social activities and other occupations that do not constitute activities. This list is classified according to the kind of activity, but also according to the logical and possible order of development of these activities during the day, from the moment a household member wakes up until they go to bed. These activities are classified under eight categories. The code of each category appears between brackets before the activity:

(1) Economic activities for the market,
(2) Non-market economic activities,
(3) Domestic activities,
(4) Social activities,
(5) Social activities of ceremonial type, and other social activities,
(6) Transport, travelling,
(7) Leisure,
(8) Studying and education,
(9) Other activities not classified.

1. (8) Sleeping
2. (8) Resting, doing nothing
3. (8) Taking bathe, dressing
4. (8) Eating meals
5. (3) Washing dishes
6. (3) Upkeep of dwelling
7. (3) Ironing
8. (3) Washing clothes
9. (3) Other household maintenance
10. (3) Drying food products
11. (2) Fetching water
12. (2) Preparing meals for the household
13. (2) Fetching firewood
14. (3) Shopping
15. (6) Travelling
16. (3) Taking care of children
17. (3) Taking care of elderly, sick, etc.
18. (1) Main activity................................/_/_/_/_/
19. (1) Secondary activity 1..................../_/_/_/_/
20. (1) Secondary activity 2..................../_/_/_/_/
21. (2) Agriculture
22. (2) Gardening
23. (2) Livestock
24. (2) Fishing
25. (2) Harvesting
26. (2) Weaving
27. (2) Basketry
28. (2) Crushing
29. (2) Processing agricultural products
30. (8) Medical care
31. (5) Receiving guests (relatives, friends, neighbours)
32. (8) Shopping
33. (5) Discussing, chatting
34. (5) Visiting relatives, friends, neighbours

35. (5) Attending ceremonies, baptisms, marriages, bereavements, etc.
36. (2.5) Preparing food for ceremonies
37. (4) Participation in social meetings (political parties, religious practices, trade unions, NGOs, community organisations)
38. (7) Listening to Radio, Watching TV
39. (7) Recreational activities including dancing
40. (7) Pottery
41. Other, specify:......................